

# **SPEAC<sup>®</sup>** **SYSTEM**

## **Generalized Tonic-Clonic Seizure Detection and Warning System User's Manual**



***Be Heard***

### **Disclaimer Statements**

This User Manual must be read before installing or operating the SPEAC® System, Brain Sentinel®'s Generalized Tonic-Clonic Seizure Detection and Warning System. The purpose of this manual is to communicate information required for the operation of the SPEAC® System. The information presented in this document is recommended for use by the prescribing physician, patient, patient's family, and the patient's caregiver(s).

All patients, caregivers and service personnel should read and thoroughly understand the contents of this manual and the importance of the warnings, precautions and the operation of the SPEAC® System by Brain Sentinel® as outlined in this document.

If you do not understand the warnings, precautions, and operational requirements of this System, do not use the SPEAC® System until you have spoken with your physician and understand such information. If you do not understand this manual, discuss the medical issues with your physician, or discuss the technical product issues with Brain Sentinel®. This System is not a substitute for adequate patient supervision or medication. Please ensure that a trained caregiver is present to provide assistance when the system alarms

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# 1. SPEAC<sup>®</sup> System Indications for Use and Warnings

## 1.1 SPEAC<sup>®</sup> System Indications for Use

The SPEAC<sup>®</sup> System by Brain Sentinel<sup>®</sup> is an ambulatory system designed to monitor and analyze surface electromyography (sEMG) data to detect generalized tonic-clonic (GTC) seizures and to provide a warning signal to alert caregivers within 30 seconds of onset that a seizure is occurring. The system records and stores sEMG data for subsequent review by a trained healthcare professional.

The SPEAC<sup>®</sup> System by Brain Sentinel<sup>®</sup> is intended for use in patients who have an arm circumference of at least 16 cm at the biceps. It may be used in the home or healthcare facilities for monitoring during the day, night, or for continuous monitoring.



## 1.2 Warnings for the SPEAC<sup>®</sup> System

Precautions and special care must be taken when using the SPEAC<sup>®</sup> System. Here is a list of specific product warnings that the user must keep in mind for the proper use and functioning of the System.

### 1.2.1 Ensure Proper Placement of the SPEAC<sup>®</sup> Detection Device

Proper placement of the SPEAC<sup>®</sup> Detection Device is directly centered over the bulge of the biceps muscle. This placement is essential to ensure the user is properly monitored and in order to receive seizure alarms. Specific instructions for proper placement can be found in Section 4 of this User Manual and on the Setup Wizard Video on the SPEAC<sup>®</sup> Laptop Base Station.

### 1.2.2 Never Attach Unauthorized Connections and/or Equipment to Any Part of the SPEAC<sup>®</sup> System

Only authorized equipment sent to you by Brain Sentinel<sup>®</sup> should be used with the SPEAC<sup>®</sup> System.

- Connecting the USB connector on the SPEAC<sup>®</sup> Detection Device to equipment not authorized by Brain Sentinel<sup>®</sup> may result in unacceptable hazards to the operator or may damage the Detection Device, as well as, the unauthorized equipment.
- Connecting the SPEAC<sup>®</sup> Laptop Base Station to an AC Adapter that is not supplied by Brain Sentinel<sup>®</sup> may result in unacceptable hazards to the operator, and may damage the SPEAC<sup>®</sup> Laptop Base Station and the unauthorized equipment.
- Before the SPEAC<sup>®</sup> Detection Device is connected to the SPEAC<sup>®</sup> Laptop Base Station for charging or configuration,
  1. Ensure there is no unauthorized equipment connected to the SPEAC<sup>®</sup> Laptop Base Station. Review Section 3 for installation requirements.
  2. Ensure the AC Adapter is connected to both the SPEAC<sup>®</sup> Laptop Base Station and the wall outlet (SUPPLY MAINS).
- Connecting unauthorized equipment to the spare IO ports on the SPEAC<sup>®</sup> Base Station, can result in unacceptable hazards to the operator, and can damage the SPEAC<sup>®</sup> Detection Device and the unauthorized equipment.

### 1.2.3 Never Connect Any Part of the SPEAC<sup>®</sup> System to Equipment That Is Not Part of the SPEAC<sup>®</sup> System

Connecting the USB connector on the SPEAC<sup>®</sup> Detection Device to equipment not authorized by Brain Sentinel<sup>®</sup> may result in unacceptable hazards to the operator, and may damage the SPEAC<sup>®</sup> Detection Device and the unauthorized equipment.

Connecting the CradlePoint Wireless Router to an AC Power Adapter that is not authorized by Brain Sentinel<sup>®</sup> may result in unacceptable hazards to the operator, and may damage the SPEAC<sup>®</sup> Laptop Base Station and the unauthorized equipment. Use only the AC power adapter provided.

The CradlePoint Wireless Router has an ON/OFF switch. It can be turned on/off by this switch. Isolation of the router from the wall outlet (SUPPLY MAINS) can be safely done by disconnecting the detachable power inlet cord from the router.

### 1.2.4 Ensure Uninterrupted System Connections

In order to ensure continuous monitoring, there are three critical connections within the SPEAC<sup>®</sup> System that should never be interrupted:

1. *Power supply from the wall to the SPEAC<sup>®</sup> Laptop Base Station*
2. *Wi-Fi connection between the SPEAC<sup>®</sup> Detection Devices and the SPEAC<sup>®</sup> Laptop Base Station*

A continuous power supply to the SPEAC<sup>®</sup> Laptop Base Station helps ensure that the patient is being continuously monitored for seizure activity.

A continuous Wi-Fi connection between the SPEAC<sup>®</sup> Detection Device and the SPEAC<sup>®</sup> Laptop Base Station helps ensure that the patient is being continuously monitored for GTC seizure activity. If the patient leaves the Wi-Fi zone, the SPEAC<sup>®</sup> Laptop Base Station will alarm and the monitoring is interrupted.

As part of the initial installation of the SPEAC<sup>®</sup> System in the home, you should test the boundaries of the Wi-Fi connection between the SPEAC<sup>®</sup> Detection Device and the SPEAC<sup>®</sup> Laptop Base Station. See Section 4.3 of this User Manual for further details about checking the Wi-Fi limits in your home or facility.

3. *Connection to the internet via the CradlePoint Access Point/Wireless Router*

Internet functionality is represented by the “Web Interface” tile on the SPEAC<sup>®</sup> Laptop Base Station screen. If you are without remote alarms you may need to take additional measures to ensure safety in case a seizure occurs.

Remote alarms may only be issued when the network is connected to the internet. When not connected to the internet, the system will alarm those within audible or visual range of the system. The SPEAC<sup>®</sup> Detection Device and the SPEAC<sup>®</sup> Laptop Base Station will still alarm should a seizure occur.

Whether or not the SPEAC<sup>®</sup> System is connected to the internet, the SPEAC<sup>®</sup> System is not a substitute for adequate patient supervision or medication. Please ensure a competent, responsible, trained caregiver is present to provide assistance to the patient when the SPEAC<sup>®</sup> System alarms.

### 1.2.5 Maintain the Charge of the SPEAC<sup>®</sup> Detection Device batteries

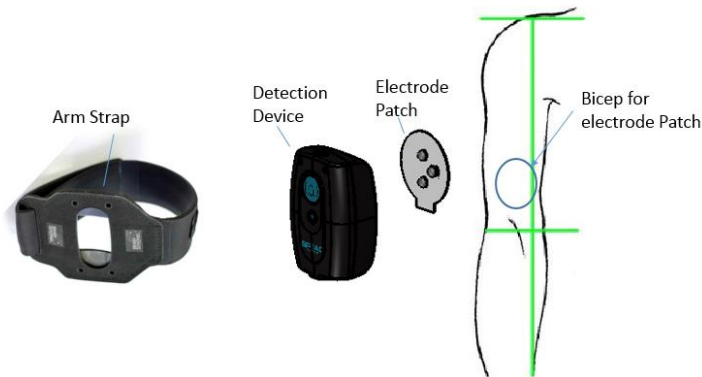
Maintaining the SPEAC<sup>®</sup> Detection Device batteries charged at all times is critical for their ongoing proper performance. Like most rechargeable batteries, the SPEAC<sup>®</sup> Detection Device battery should be charged at least once every 4-6 weeks or kept at 50% charged when not being used. Fully charged batteries

discharge when they are left unused and will lose effectiveness if they are left fully discharged for longer than four (4) weeks. Maintaining their charge will prolong the life of the batteries.



### 1.2.6 Properly Apply SPEAC® System Parts to the Biceps:

When properly placed, the SPEAC® System monitors the patient for generalized tonic-clonic seizures. There are three components of the SPEAC® System that are directly or indirectly applied to the biceps. These parts are the electrode patch, the SPEAC® Detection Device and the SPEAC® Arm Strap. See Figure 1A, Section 4 of this User Manual and the Wizard Video on the SPEAC® Laptop Base Station for additional help for proper placement.



**Figure 1A. Applied Parts Include: SPEAC® Arm Strap, SPEAC® Detection Device and Electrode Patch**



**Figure 1B.  
Electrode  
Sockets**

**Electrode Patch:** A reliable electrical connection between the SPEAC® Detection Device and the electrode patch is necessary to achieve a good surface EMG (sEMG) signal for analysis by the SPEAC® Detection Device. The electrode patch snaps into the electrode sockets on the back of the SPEAC® Detection Device (See Figure 1B). The SPEAC® Detection Device comes into direct physical contact with the patient’s skin through the electrode patch on top of the biceps muscle. It is important that the electrodes on the electrode patch make physical contact with the patient’s skin over this part – AND ONLY THIS PART – of the biceps.

Be gentle when applying and removing the electrode patch from the biceps. . Gently remove the electrode patch by slowly peeling it from the outside edge. A small amount of water may be used to dilute the electrode adhesive. Skin irritation may occur due to prolonged exposure to the electrode patch, or from frequent electrode patch changes. Never apply the electrode patch to open or irritated skin.

**Grounding:** The SPEAC® Detection Device enclosure is marked with the internationally accepted symbol for a Type BF Applied Part indicating that all of the applied parts are electrically isolated from ground in order to help avoid electrical shock and harmful leakage currents.

**SPEAC® Arm Strap:** The SPEAC® Arm Strap should only be placed on the arm, and is designed to gently support the SPEAC® Detection Device. It should be gently strapped to the arm, allowing space for two fingers to loosely fit between the SPEAC® Arm Strap and the skin. Should discoloration or swelling of the hand occur, or other injury, immediately discontinue use and seek medical attention.

Never place the SPEAC® Arm Strap around the neck. Keep the arm strap away from infants and children when not in use to avoid the risk of strangulation.

### 1.2.7 Avoid Liquid, Moisture and Submersion in Water

While the SPEAC® Detection Device exterior plastic casing was designed to be used in the shower, liquid may damage the electronics inside the SPEAC® Detection Device. Prevent liquids from being spilled into the SPEAC® Detection Device via the USB port, please contact Brain Sentinel® for a replacement.

The SPEAC® Detection Device is never to be submerged in water, e.g., bath tub, swimming pool, or kitchen sink, etc. The detection device cannot monitor for Generalized Tonic-Clonic Seizures while submerged. If you should have any questions regarding whether the SPEAC® Detection Device has been compromised, contact Brain Sentinel®.

Finally, take care not to spill liquid on the SPEAC® Laptop Base Station. Doing so may damage its internal electronics rendering the entire system unusable.

### 1.2.8 Avoid Use in a Magnetic Resonance Imaging (MRI) System



The SPEAC® System is not safe for use with an MRI. Do not allow any part of the SPEAC® System in or near an MRI system.



### 1.2.9 Use of Radio Frequency (RF) Energy

The SPEAC® System contains a transmitter and receiver of RF energy through an antenna located on the interior of the Detection Device below the status LEDs.

For more information about the research related to RF energy exposure, see the FCC's Radio Frequency Exposure page at [www.fcc.gov/oet/safety](http://www.fcc.gov/oet/safety)

### 1.2.9 Radio Frequency (RF) Energy Interference

Radio frequency emissions from other electronic equipment can negatively affect the operation of the other electronic equipment and potentially cause them to malfunction. The SPEAC® System is designed, tested, and manufactured to comply with regulations governing radio frequency emissions. There is no known electronic equipment with which the SPEAC® System interferes. However, if the wireless transmitters and/or other electrical circuits in the SPEAC® System are suspected of causing interference in other electronic equipment, take the following precautions:

- Relocate the SPEAC® Detection Device that is experiencing the interference.
- Increase the distance between the SPEAC® Laptop Base Station and/or Wi-Fi Hotspot and the equipment experiencing the interference.
- Connect the SPEAC® Laptop Base Station and/or Wi-Fi Hotspot to a wall outlet (SUPPLY MAINS) on a circuit different from that to which the equipment experiencing the interference is connected.
- Always beware of locations that restrict the use of RF devices.

### 1.2.10 FCC Compliance

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT! Changes or modifications not expressly approved by Brain Sentinel, Inc. could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

### 1.2.11 IC Compliance

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

*CAN ICES-3 (B)/NMB-3(B)*

This equipment complies with radiation exposure limits set forth for uncontrolled environment.

### Français

Cet appareil est conforme avec Industrie Canada, exempts de licence RSS ou les normes. Opération est soumise aux deux conditions suivantes:

- (1) cet appareil ne doit pas causer des interférences et
- (2) cet appareil doit accepter toute interférence reçue, y compris les interférences pouvant entraîner un fonctionnement non désiré de l'appareil.

Cet équipement est conforme aux limites d'exposition aux radiations établies pour un environnement non contrôlé.

### 1.2.12 Do Not Make Modifications to Any Part of the SPEAC<sup>®</sup> System

No modification of this System is allowed, unless performed by authorized Brain Sentinel<sup>®</sup> personnel. Unauthorized modification of the equipment may result in hazards to the end user. If this equipment is modified (by authorized personnel), appropriate inspection and testing will be conducted to ensure the appropriate use of the equipment.



The SPEAC® Laptop Base Station is optimized for the functions performed by the SPEAC® System. Do not install applications, uninstall applications, or alter the configuration or environmental variables of this laptop computer unless instructed by Brain Sentinel® personnel or the accompanying documents.

### 1.2.13 Disposal and Return of the SPEAC® System



The SPEAC® System components contain Lithium-Ion Polymer batteries and other electronics components, and must not be disposed of with other household waste. When the SPEAC® System has reached the end of its life, please return it to Brain Sentinel® for proper disposal. See Section 5 of this User Manual for additional details on how to return the System to Brain Sentinel®.

## 2. The SPEAC® System Overview

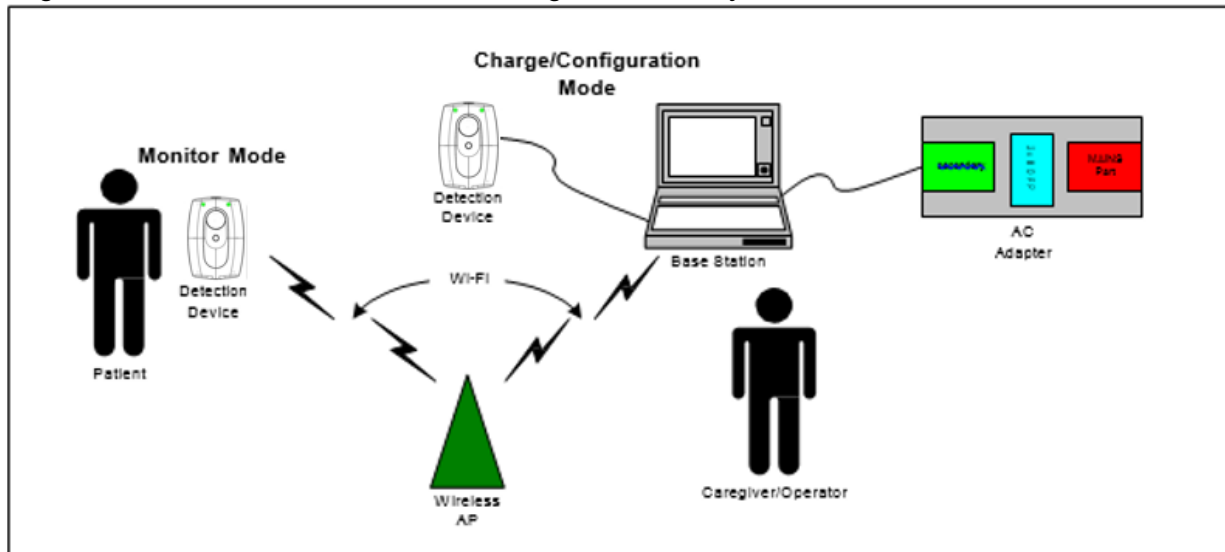
*Figure 2A. The Sensing, Portable, EMG, Analysis and Characterization - SPEAC® System*



The SPEAC® System by Brain Sentinel® is a surface electromyography (sEMG)-based ambulatory system that detects and alarms for generalized tonic-clonic seizures at home and in healthcare facilities. The SPEAC® System detects generalized tonic-clonic seizures in real-time, providing alerts within seconds. It also provides physicians with a record of the patient’s sEMG history using the system with accurate seizure counts and seizure history allowing for characterization by the physician.

The SPEAC® System continuously monitors and analyzes surface electromyography data to detect, in realtime, generalized tonic-clonic (GTC) seizures, both primary and focal onset with secondary generalization. Once the diagnostic algorithm detects a seizure, the system rapidly alerts and warns patients and their designated caregivers while continuously and accurately recording the EMG data of the patient for clinical review by the physician. The GTC Seizure Detection and Warning System helps give both patients and their caregivers greater security and peace of mind.

*Figure 2B. Schematic of the Interfaces Enabling the SPEAC® System*



## 2.1 How the SPEAC® System Components Work Together As a System

The components of the SPEAC® System by Brain Sentinel® that will arrive to you in the delivery box are as follows:

- Two (2) SPEAC® Detection Devices. Details in Section 2.2.
- One (1) SPEAC® Laptop Base Station. Details in Section 2.3.
- One (1) CradlePoint Access Point/Wireless Router. Details in Section 2.4.
- Two (2) SPEAC® Bioprene® Arm Straps. Details in Section 2.5.
- Twenty (20) Daily Electrode Patches. Details in Section 2.6.
- One (1) Pack of Oil-Removing Wipes. Details in Section 2.7.



**Figure 2C. SPEAC® Detection Devices**

## 2.2 SPEAC® Detection Devices

The SPEAC® Detection Device is a battery-operated device consisting of electrical inputs for surface electromyography (sEMG) and a signal processing unit. The SPEAC® Detection Device, designed for daily use, is secured to the biceps. The SPEAC® Detection Device runs on a diagnostic algorithm that continuously monitors and analyzes the patient's EMG signals, and determines whether the signals from the measured frequency bands are characteristic of a generalized tonic-clonic seizure. Once a generalized tonic-clonic seizure is detected, the device provides instant alerts. The SPEAC® Detection Device also provides operational alerts – for low battery, critical battery, loose electrodes

and lost connection with the SPEAC® Laptop Base Station – to ensure the system functions properly.

Two SPEAC® Detection Devices are provided. One SPEAC® Detection Device will be connected to the patient to monitor EMG activity. The other will be connected to the SPEAC® Laptop Base Station for charging the battery as well as configuration and data transfers. When the monitoring SPEAC® Detection Device connected to the patient needs charging, it is swapped with the SPEAC® Detection Device that is charging on the SPEAC® Laptop Base Station. The SPEAC® Detection Device contains a highly integrated microcontroller that is programmed at the factory. The firmware version of SPEAC® Detection Device is managed by the SPEAC® Laptop Base Station.

The SPEAC® Detection Devices are powered by an internal, rechargeable battery which has the capacity for 24 hours of monitoring. The battery requires connecting the SPEAC® Laptop Base Station to the micro-USB connector on the SPEAC® Detection Device using the USB cable provided.

You should only use the SPEAC® Laptop Base Station to recharge the SPEAC® Detection Devices not only to minimize the risk of electrical hazards, but also to ensure that the recorded sEMG data are uploaded to the SPEAC® Laptop Base Station.

### 2.2.1 SPEAC® Detection Device Component List Overview

The SPEAC® Detection Device is composed of the following:

- Enclosure: Manufactured by Brain Sentinel®
- Pickup PCBA: Manufactured by Brain Sentinel®
- EMG PCBA: Manufactured by Brain Sentinel®
- Processor PCBA: Manufactured by Brain Sentinel®
- Wi-Fi Module and Antenna: FCC compliant manufactured by Redpine® Signals
- Battery: Rechargeable lithium-ion with PCM manufactured by Varta®
- Audible UI: piezo speaker manufactured by PUI Audio, Inc.

- Haptic UI: vibration motor manufactured by PUI Audio, Inc.
- Input UI: Membrane Keypad manufactured by Valmark Interface Solutions®

## 2.3 The SPEAC® Laptop Base Station

The SPEAC® Laptop Base Station is a computer that serves as the control hub for the entire SPEAC® System. It displays information received from the SPEAC® Detection Devices worn on the arm. The SPEAC® Laptop Base Station maintains wireless communication with the SPEAC® Detection Device that is applied to the center of the belly of the patient's biceps. The SPEAC® Laptop Base Station provides audible and visual alarms to a caregiver when a generalized tonic-clonic seizure is detected by the SPEAC® Detection Device as well as other system statuses. The SPEAC® Laptop Base Station is also used to charge and, configure the SPEAC® Detection Device. It also downloads the patient's sEMG data from SPEAC® Detection Device while connected via the provided USB cord. The SPEAC® Laptop Base Station also provides operational alerts to keep the system operating effectively.



**Figure 2D. SPEAC® Laptop Base Station**

The SPEAC® System utilizes the computer's LCD, sound card, USB and Wi-Fi hardware integrated on the computer. The SPEAC® Laptop Base Station is installed with the Windows 8.1® Operating System on an Acer Aspire E3-111-P60S laptop. In addition, Brain Sentinel® installs proprietary software applications and custom configurations on SPEAC® Laptop Base Station, including its "SPEAC® BaseStationApp". The version of the application software is managed by a utility integrated within the application. Refer to section 2.9 for more details on software version control. No other applications should be loaded to the SPEAC® Base Station without the approval of Brain Sentinel®.

## 2.4 Cradlepoint Wireless Router



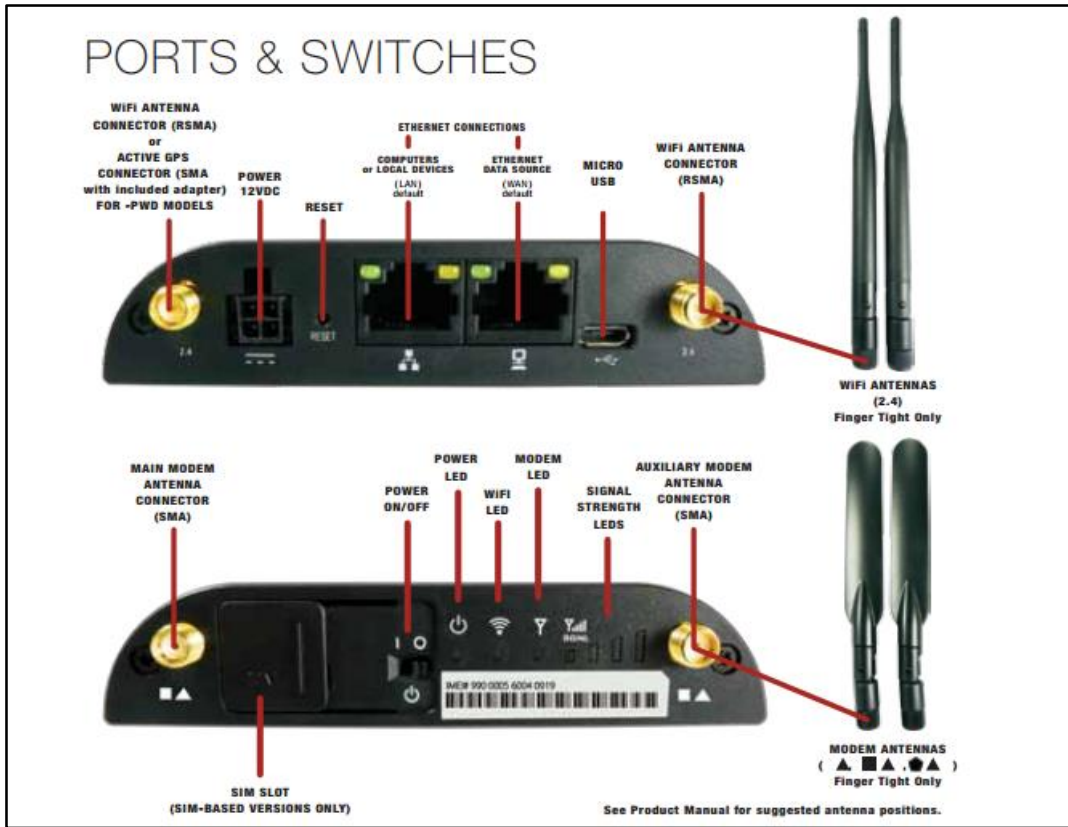
**Figure 2E. SPEAC® Laptop Base Station Alongside the CradlePoint Wireless Router**

**The CradlePoint Wireless Router** performs two key functions. First, it maintains the communication link between the SPEAC® Detection Device and the SPEAC® Laptop Base Station. Second, it maintains constant communication between the SPEAC® Laptop Base Station and Brain Sentinel's servers. Both of these communication links are critical for the proper functioning of the SPEAC® GTC Seizure Detection and Warning System.

### 2.4.1 CradlePoint Wireless Router Indicator and Control Functions

The SPEAC® System requires a limited subset of the indicator and control functions available on the router. See Figure 2F for the ports and switches used by the router. The required functions are summarized in Table 2A.

**Figure 2F. CradlePoint Wireless Router Ports and Switches**



**Table 2A. CradlePoint Wireless Router LED Status**

Indicator	Color	Meaning
Power LED	Blue (solid)	Power is on
Power LED	No Light	Power is off
Wi-Fi LED	Green (solid)	Wi-Fi is on
Wi-Fi LED	No Light	Power is off
Modem LED	Green (solid)	DSL is on and operating normally
Modem LED	Green (blinking)	Connecting
Modem LED	Amber (solid)	Not Available
Modem LED	Amber (blinking)	Cellular data connection error
Modem LED	No Light	Modem is off
Signal Strength LED	Green	More bars mean a stronger signal

**2.4.2. CradlePoint Wireless Router Technical Characteristics**

**2.4.2.1. CradlePoint Wireless Router Mechanical Characteristics**

- Height: 3.3-in"
- Width: 4.0-in"
- Depth: 0.9-in"
- Weight: 7.2 oz

**2.4.2.2. CradlePoint Wireless Router Electrical Characteristics**

- External Modem and Wi-Fi Antennas Two Ethernet Ports
- (LAN/LAN or WAN/LAN)

- Wi-Fi 802.11 with Full Security Fully Integrated Router/Bridge Integrated 3G/4G modem Ruggedized Metal Housing
- Certified for shock and vibration in accordance with MIL STD 810G and SAE J1455 External 3G/4G and Wi-Fi Antennas
- Two Ethernet Ports (LAN/LAN or WAN/LAN)
- Wi-Fi 802.11 with Full Security Non-Wi-Fi version available Built-in GPS with NMEA Output
- Technology: LTE, EVDO Rev A
- Downlink Rates: LTE 50 Mbps, EVDO 3.1 Mbps (theoretical)
- Uplink Rates: LTE 50 Mbps, EVDO 1.8 Mbps (theoretical)
- Frequency Bands: LTE Band 13 (700 MHz); CDMA EVDO Rev A/1xRTT (800/1,900 MHz)
- Module Power: LTE 23 dBm +/- 1, EVDO 24 dBm +/- 1 (typical conducted)
- Module: Sierra Wireless MC7750
- Module Antennas: two SMA male (plug), 1 dBi (LTE), 2 dBi (CDMA) gain; finger tighten only; support for GPS on aux connection
- GPS: standalone GPS support
- Power: Idle: typical=350mA@12V(4.2W) worst case=700mA@12V(8.4W)
- Tx/Rx: typical=600mA@12V(7.2W)
- worst case=1200mA@12V(14.4W)
- Industry Standards & Certs: FCC, Wi-Fi Alliance, Verizon, Verizon NEMO/DMNR for Primary Wireless Access
- Certification Part Number: IBR600LE-VZ
- See more at: <http://CradlePoint.com/products/machine-to-machine-routers/cor-ibr600-3G-4G-router#sthash.dJq3DV1C.dpuf>

#### 2.4.2.3. CradlePoint Wireless Router Software Characteristics

- Managed by CradlePoint, but updates are not mandatory.

## 2.5 SPEAC® Arm Strap



The SPEAC® Arm Strap is used to secure the SPEAC® Detection Device to the patient's arm. The use of the SPEAC® Arm Strap is always recommended while the patient is engaged in any activity that could result in the unintended release of the SPEAC® Detection Device from the biceps. This is particularly important while sleeping, showering or vigorous physical activity. Two SPEAC® Arm Straps are provided for convenience.

Figure 2G. SPEAC® Arm Strap

## 2.6 Electrode Patches Approved for Use with the SPEAC® System



The surface electrode patch has a triode configuration that provides physical contact to three equally spaced points on the skin of the patient's biceps. A supply of single-use electrode patches are included with the SPEAC® System. Additional electrode patches can be ordered from Brain Sentinel®. See Section 5 for reordering details.

Hydrogel is pre-applied to each electrode to enhance the skin-to-electrode contact. Prolonged exposure to air, heat or sunlight will

Figure 2H. Electrode Patches

dry the hydrogel prematurely. For this reason the spare electrode patches should be placed in a sealed container and stored in a cool location out of direct sunlight.

Electrode patches will need to be changed every 24 hours. Patient usage and activities may increase or decrease the use of the electrode patch.

## 2.8 Oil-Removing Wipes

Brain Sentinel® provides you with a set of oil removing wipes to be used just before placing the SPEAC® Detection Device. Never use rubbing alcohol or alcohol wipes to remove the oil from your biceps. Alcohol interacts with the hydrogel, thereby damaging the electrode patches. This can leave you unmonitored for generalized tonic-clonic seizures. In addition, the alcohol can irritate the skin.

You can ask for additional wipes from Brain Sentinel's customer service or you may use non-alcoholic wipes found at your local pharmacy or grocery store.

## 2.9 Cables Included with the SPEAC® System



### 2.9.1 USB Cable

A USB-A to mini USB-B cable is used to communicate data from the SPEAC® Base Station to the SPEAC® Detection Device as well as charge the SPEAC® Detection Device when not in use. The USB-A end plugs into SPEAC® Laptop Base Station and the USB-B end plugs into the detection device. (See Figure 2I top image).



### 2.9.2 AC Adapter for the SPEAC® Laptop Base Station

The SPEAC® Laptop Base Station should remain connected to the AC adapter at all times, but can be powered by the internal battery for convenience for limited periods of time. In this case or during power outages, the SPEAC® Laptop Base Station's internal battery can maintain operation for a minimum of 5 hours when it is fully charged. Charge time is less than 6 hours. (See Figure 2I middle image).

The SPEAC® Laptop Base Station has the following specifications:

- Manufacturer: Emerson
- Model #: DP4018N2M
- AC Input Voltage: 100-240V
- Frequency Input: 50/60 Hz
- DC Output Voltage: 18VDC±10%
- Output Current: 2.2 A
- Class II, 2x MOP



**Figure 2I. From Top to Bottom: USB, SPEAC® Laptop Base Station, and Wireless Router**

The AC Adapter for the SPEAC® Laptop Base Station does not have an ON/OFF switch. Isolation of the AC Adapter from the wall outlet (SUPPLY MAINS) can be safely done by disconnecting the detachable power cord from the AC Adapter. For this reason, the AC Adapter should be positioned to allow unobstructed access to the inlet cord. This AC Adapter satisfies the isolation requirements in the 60601-1-2, 3<sup>rd</sup> Edition standard for use with medical-electrical equipment.

The SPEAC® Laptop Base Station's AC Adapter is a Class II electrical equipment and has been approved by the relevant and required agencies for use in a medical-electrical system. The construction of these

components provides protection against electric shock. There is no requirement or provision in the SPEAC® System for protective grounding.

The AC Adapter supplied with the SPEAC® System has been tested and approved by Brain Sentinel® for use with the SPEAC® System. Only use Brain Sentinel-approved AC adapters with the SPEAC® System.


### 2.9.3 An AC Adapter for the CradlePoint Wireless Router.

The CradlePoint Wireless Router uses a power adapter for constant mains power and is capable of 240v. The CradlePoint Router AC Power Adapter has the following specifications:

- Manufacturer: CradlePoint
- Model #:HK-AB120A150US
- Input Voltage: 100-240V
- Input Frequency:50/60Hz
- Input Current: < 0.8 A
- Output Voltage: 12VDC
- Output Current: 1.5A(max)

(See Figure 2I bottom image).

## 2.10 Software and Firmware Versions

 Brain Sentinel Base Station v1.10.0 | Reporting to BrainSentinel.com

### *Figure 2J. SPEAC® Laptop Base Station Update Utility Screenshot*

- The firmware installed on the SPEAC® Detection Device can be found on the startup banner displayed when the SPEAC® BaseStationApp opens, and on the Wi-Fi Status of the SPEAC® BaseStationApp
- The software version of the SPEAC® BaseStationApp can be found on the startup banner displayed when the SPEAC® BaseStationApp opens, and on the title bar of the application.
- The version of the SPEAC® BaseStationApp Update utility can be found on the startup banner displayed when the SPEAC® BaseStationApp opens.



### 3. Installing the SPEAC® System

When you first start using the SPEAC® System, it is important to ensure that your environment is set up to support your monitoring. This will help ensure that you identify any issues that could impact the proper functioning of the SPEAC® System in your home.



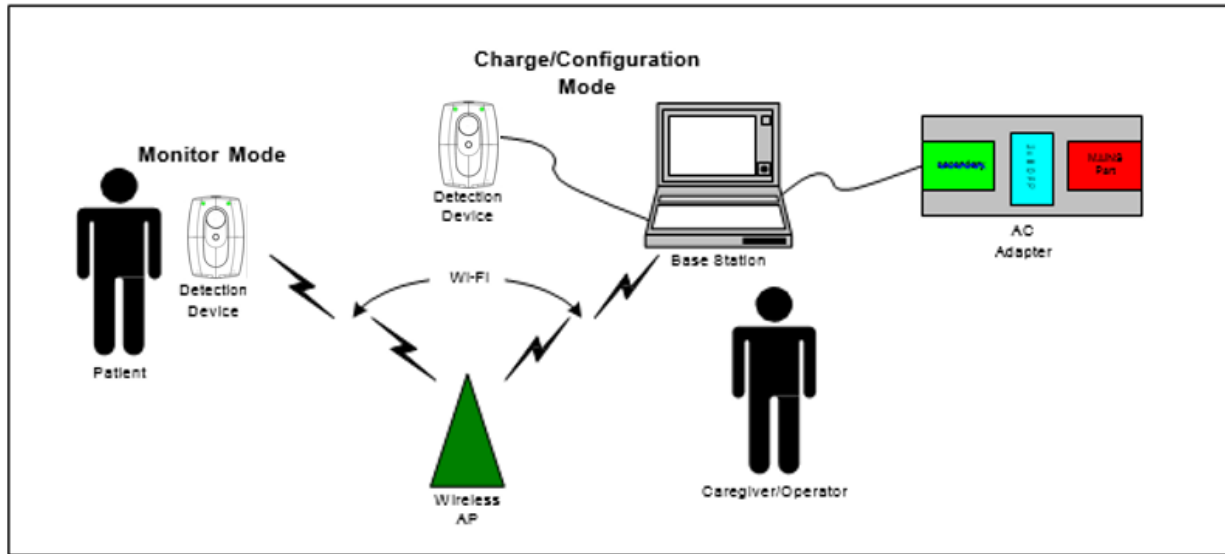
*Figure 3A. The SPEAC® System*

#### 3.1 Setup Checklist for the SPEAC® System

Before proceeding with the placement of the SPEAC® System, review the following checklist to make sure that you have everything that you need ready.

1. Unpack the box containing the individual parts of the SPEAC® System.
2. Identify each component of the SPEAC® System from Section 2 of the User Guide.
3. Follow the instructions below in Section 3 to find the best location for the CradlePoint Wireless Router and the SPEAC® Laptop Base Station.
4. Follow the instructions in Section 4 to use and configure the SPEAC® System.
5. Plug in to charge the SPEAC® Detection Device that is not being used currently on the biceps.
6. Test the Wi-Fi connection and boundary limits immediately after placing the device.
7. Set up your daily schedule to change out the SPEAC® Detection Device and electrode patches.

### 3.2 SPEAC® System Setup Requirements



**Figure 3B. The SPEAC® System Connections Diagram**

#### 3.2.1 Finding the Best Place for the CradlePoint Wireless Router

The CradlePoint router should be placed on a stable horizontal surface within 6 feet of a wall outlet. If possible, the location of the router should be in place central to the patient’s daily activities.

##### Considerations and Cautions:

- Do not place the router in areas exposed to liquids, food or temperature extremes outside normal room temperatures.
- Find a location with minimal or no activities that could damage any component in the system.
- Locate the router as far away as possible from electrical equipment or appliances, e.g., microwave ovens that can generate Wi-Fi signal interference.
- Avoid locations where physical obstructions might weaken the Wi-Fi signals, e.g., metal shielded wall.
- Avoid locations where reflective or metal surfaces, such as mirrors, metal file cabinets, and metal counter tops that can reduce the network range and performance.

#### 3.2.3 Finding the Best Place for the SPEAC® Laptop Base Station

The SPEAC® Laptop Base Station should be placed on a stable horizontal surface within 6 feet of a wall outlet (SUPPLY MAINS).

##### Considerations and Cautions:

- The surface should have enough area for the SPEAC® Laptop Base Station, the AC adapter and a connected SPEAC® Detection Device. The location should allow efficient use of SPEAC® Laptop Base Station. We recommend a minimum 2ft by 2ft area.
- Restrict activities in the vicinity of SPEAC® Laptop Base Station that could distract the operator. Any activity that could potentially damage the SPEAC® Detection Device should be prohibited in the vicinity of the SPEAC® Laptop Base Station.
- The SPEAC® Laptop Base Station should be located within the audible range of the caregiver. Ambient noise levels should be minimized so the audible alarms generated by the SPEAC® Laptop Base Station are heard above all other sounds.

- The operator will need to view the information displayed on the SPEAC® Laptop Base Station LCD screen and enter data using the keyboard. The ambient light should be evaluated for efficient use of the SPEAC® Laptop Base Station keyboard and the LCD screen.
- The SPEAC® Laptop Base Station should not be located in areas exposed to liquids, food or temperature extremes outside normal room temperatures. Potential activities in the vicinity that could distract the operator or damage any component in the system should also be taken into consideration when choosing a location.

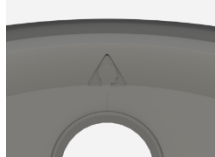


**Figure 3C. The SPEAC® Detection Device Front View**

### 3.3 SPEAC® Detection Device Buttons and LEDs

The SPEAC® Detection Device has a simple set of buttons and LED lights to make it easy to operate and understand. See Section 4.6.1 in this User Manual for a detailed description of the LED light settings.

#### 3.3.1 Control Functions



**Figure 3D. Head Icon on back of SPEAC® Detection Device**

The SPEAC® Detection Device is initially worn on the dominant arm. The Head Symbol (left) on the back of the SPEAC® Detection Device is always positioned toward the patient's head.

#### 3.3.2 Power (ON/OFF) Button



**Figure 3E. The SPEAC® Detection Device Top View**

The SPEAC® Detection Device power button is on the top as seen in Figure 3D. Briefly pressing the ON/OFF button will turn on the device.

To turn off the device, the ON/OFF button must be pressed and held for approximately 8 seconds.

When the SPEAC® Detection Device turns on, it will conduct what is called a "Power-On Self-Test" (POST) which will conclude with both LEDs being white. The speaker will beep several times and will be followed by a quick vibrations from the haptic feedback motor. After the POST is completed and after the Electrode Setup Process has been completed (See Section 4.X), the SPEAC® Detection Device will start monitoring the

body's signals present at the EMG connections, join the assigned network, and perform other functions related to its proper functioning.

The SPEAC® Detection Device is "Monitor Mode" while both LED lights are in solid green



**Figure 3F. The SPEAC® Detection Device Front View**

When the SPEAC® Detection Device is not in "Monitor" mode, it should be connected to the SPEAC® Laptop Base Station for downloading sEMG data, Detection Device firmware verification and battery charging and downloading sEMG data.

### 3.3.3 Panic Button

The SPEAC® Detection Device has two buttons on the face of it. See Figure 3E. The large button is the Panic button, marked with a bell. Use this if you feel that you are about to have a seizure. You must push and hold the Panic button for 3-5 seconds for it to alarm. Remember that if you have a generalized tonic-clonic seizure and do not push the button, the SPEAC™ System is designed to visually and audibly alarm automatically on both the SPEAC® Detection Device and SPEAC® Laptop Base

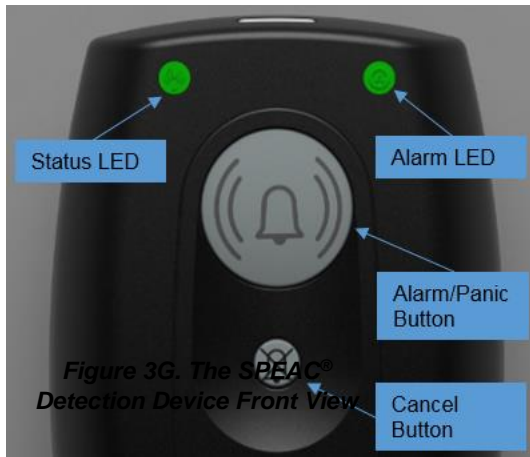
Station.

### Automatic Seizure Alarm Triggered by SPEAC® Detection Device

When a Generalized Tonic-Clonic Seizure is detected by the SPEAC® Detection Device, a Seizure Alarm is sent to the SPEAC® Laptop Base Station. A seizure alarm and vibration will be generated by the SPEAC® Detection Device. If the patient believes that the Seizure Alarm is incorrect, the alarm can be cancelled by pressing the Cancel Button twice on the SPEAC® Detection Device.

### Manual Seizure Alarm Triggered by the Panic Button

When a patient presses and holds the "Panic" Button for five (5) seconds, a Seizure Alarm is sent the SPEAC® Laptop Base Station. The "Seizure has been detected" message will be show on the EMG Status window in red. The SPEAC® Detection Device will generate an alarm tone and vibration just as if the Automatic Seizure Alarm had activated. If the patient mistakenly triggers a Seizure Alarm via the Panic Button, the Seizure Alarm can be cancelled by pressing the Cancel Button twice. See the next section, 3.3.4 for instructions on cancelling a Seizure Alarm.



**Figure 3G. The SPEAC<sup>®</sup>  
Detection Device Front View**

### 3.3.4 Cancel Button

The face of the SPEAC<sup>®</sup> Detection Device has 2 lights: a Wi-Fi Status light on the left and an Electrode Status light on the right. When Wi-Fi Status light is green it indicates that it is wirelessly connected to your SPEAC<sup>®</sup> Laptop Base Station. When the Electrode Status light is green, the electrode patch has good contact with your skin. It does not mean that is necessarily properly placed. See section 4.6.1 for a description of the LED states.

The LED on the right is called the Patient Connection LED and indicates the status of the electrode patch's connection to the patient's skin. The Wi-Fi and Patient Status LEDs should both be green when the SPEAC<sup>®</sup> Detection Device and Electrode Patch are properly connected to the patient and when the SPEAC<sup>®</sup> Detection Device is communicating wirelessly to the SPEAC<sup>®</sup> Laptop

Base Station.

Each LED has three colors to be used to indicate the Wi-Fi Status and Patient Status to the patient and caregivers. The detailed description of the Patient Status LED states can be found in section 4.6.1.

If the Patient Status LED indicates a condition that is NOT described in section 4.6.1, turn the SPEAC<sup>®</sup> Detection Device off and immediately call Brain Sentinel<sup>®</sup>.

The small button marked with a crossed-out bell is the Cancel button as seen on Figure 3G. Use this if the SPEAC<sup>®</sup> System alarms for a seizure incorrectly and you are not having a seizure.

To use the Cancel button you should perform the following sequence:

1. Press the Cancel button for 1 second.
2. Release the Cancel button for about 1 second.
3. Press the Cancel button again for 1 second.

This will cancel the audible and vibration alarms generated by the SPEAC<sup>®</sup> Detection Device and the SPEAC<sup>®</sup> Laptop Base Station.

For operational alarms (Loose Electrode, Critical Battery or Wi-Fi Connection Out-of-Range), the Cancel button will only shortly delay them like a snooze button on an alarm clock. The alarm will go off again and can only be stopped once the issue has been resolved.

### 3.3.5 LED Indicators



**Figure 3H. The SPEAC® Detection Device Front View**

The face of the SPEAC® Detection Device has two lights: a “Status” LED light on the left and an “Alarm” LED light on the right.

When the “Status” LED is green, it indicates two connections are performing correctly.

1. the SPEAC® Detection Device is wirelessly connected to the SPEAC® Laptop Base Station and
2. the electrode patch has good contact with your skin. It does not mean that is necessarily properly placed on the biceps. The Alarm LED is to show alarm condition when it becomes red and flashing

The “Status” LED is used to show three statuses. When this LED is green. All three are operating normally. The three statuses are

1. Wi-Fi Status
2. Electrode Status
3. Battery Status..

A detailed description of the Status LED and Alarm LED states can be found in section 4.6.1.

If the Status or Alarm LED indicates a condition that is NOT described in section 4.6.1, take note of the colors and immediately call Brain Sentinel®.

### 3.3.6 Audio and Haptic Feedback

A speaker and an internal haptic feedback motor are used for additional feedback to the patient and caregiver when in close proximity to the patient.

- **Audio Feedback:** A low-power speaker is used to generate audible alarms for the patient and caregivers in close proximity.
- **Haptic Feedback:** A low-power vibratory motor is used to generate haptic feedback (vibration) to the patient.

## 3.4 SPEAC® Laptop Base Station’s Indicator and Control Functions



**Figure 3I. The SPEAC® Laptop Base Station**

#### Power Button

The Power button is located in the upper left corner of the keyboard (see Figure 3H). Pressing this button will turn on the SPEAC® Laptop Base Station when it is off. When the SPEAC® Laptop Base Station is on, pressing this button will turn it off.

#### Touchpad

The touchpad is a touch sensitive pointing device which functions like a computer mouse. Use the touchpad to navigate within the SPEAC® BaseStationApp application as well as the required Windows 8.1® control functions.




## Display

The SPEAC® BaseStationApp displays visual information, alarms and messages will appear on the SPEAC® Laptop Base Station's LCD display. See Section 9.9 for details on the SPEAC® BaseStationApp application indicators and control functions.

## Status Indicators

The SPEAC® Laptop Base Station has three status indicators located at the lower left corner of the keyboard surface. Each Status is described in Table 3A.

**Table 3A. The SPEAC® Laptop Base Station LED Indicators**

Indicator	Description
	Computer Power Indicator. LED will be blue when the Laptop is operational
	Computer Battery Indicator. It indicates the Laptop's battery status. The LED will be yellow when the Laptop is charging and blue when the battery is fully charged. The LED will be off when the Laptop is running on battery (AC Adapter is disconnected from Laptop or AC input to the adapter is disconnected.)
	Wi-Fi Status Indicator. Indicates the status of the Wi-Fi hardware. If the LED is off the Wi-Fi hardware is disabled or is not working properly. If the LED is orange, the Wi-Fi is on

## 3.5 Safe Operating Conditions for the SPEAC® System

All patients, operators, caregivers, and service personnel must read and thoroughly understand the contents of this Instruction for Use of the SPEAC® System to assure safe installation, operation and transport of the SPEAC® System. Immediately contact Brain Sentinel® if there is any question regarding the operation, service, return, or disposal of this equipment (See Section 5 for contact information). If you do not understand this manual, discuss the medical issues with your physician, or discuss the technical product issues with Brain Sentinel®. Regardless, do not use the system until you have a clear understanding of how the product works and the contents of this manual. This SPEAC® System and its alarms are not a substitutes for adequate patient supervision or medication. Please ensure that a trained caregiver is present to provide assistance when the system alarms

The safety characteristics of the SPEAC® System's modes of operation are described in the following sections.

### 3.5.1 Optimal Environmental Conditions for Operating the SPEAC® System

#### 3.5.1.1 SPEAC® System Detection Device Operating Limits

- Temperature: 0° C to 35° C (32°F to 95°F)
- Humidity: 15% to 93% RH (non-condensing)
- Pressure: 106 – 70 [kPa] (1.05Atmosphere – 0.69Atmosphere)
- Altitude: -15 m to 3048 m (-49 ft to 10,000 ft) [Note: not under water, but below sea level in land]

The SPEAC® Detection Device can rise to the temperature at an uncomfortable level while using the SPEAC® Detection Device in an >35°C ambient environment.

#### 3.5.1.2 SPEAC® System Laptop Base Station Operating Limits

- Temperature: 0° C to 50° C (32°F to 122°F)
- Humidity: 15 to 93% RH (non-condensing)
- Pressure: 106 – 70 [kPa] (1.05 Atmosphere – 0.69 Atmosphere)

- Altitude: -15 m to 3048 m (-49 ft to 10,000 ft) [Note: not under water, but below sea level on land]

### 3.5.1.3 CradlePoint Wireless Router Operating Limits

- Temperature Range: -20 C to 50° C (14° F to 122° F)
- Humidity: 10% to 85% RH (non-condensing)
- Pressure: 106 – 70 [kPa] (1.05Atmosphere – 0.69Atmosphere)
- Altitude: -10 m to 3000 m [Note: not under water, but below sea level in land]

## 3.5.2 Safe Storage and Transport of the SPEAC® System

### 3.5.2.1 Environmental Condition for Safe Transport and Storage

- Temperature: 0° C to 35° C (32° F to 95° F)
- Humidity: 15% to 65% RH
- Pressure: 70 [kPa] to 106 [kPa] (0.69 Atmosphere to 1 Atmosphere)
- Altitude: -15 m to 10000 m (-49 ft to 32808 ft)

### 3.5.2.2 Battery Precautions for Safe Transport and Storage

- This product contains a rechargeable Lithium battery. DO NOT EXPOSE TO TEMPERATURES GREATER THAN 95°F (35°C) and humidity in excess of 65% RH. If the batteries have sustained prolonged exposure to high heat, contact Brain Sentinel's technical support.
- The SPEAC® Laptop Base Station has limited minimum storage temperature of 0°C.
- During extended periods of storage, charging the batteries is required to achieve the specified performance.



**Figure 3J. The SPEAC® Detection Device in the Shower**

## 3.5.3 Safe Usage of the SPEAC® System While Monitoring

### 3.5.3.1 Electro-Static Discharge Shock

The SPEAC® Detection Device is an internally powered device when it is ON and operating in the "Monitor Mode" (both LEDs are solid green). The SPEAC® Detection Device enclosure is marked with the internationally accepted symbol for a Type BF Applied Part indicating all of the applied parts are electrically isolated from ground. The patient and operator are safe from electrostatic discharge shock.



### 3.5.3.2 Ingress Protection

When a SPEAC® Detection Device is attached to the patient as instructed and its USB door is closed and locked, the SPEAC® Detection Device meets the IP47 classification. The SPEAC® Detection Device in "Monitor Mode" (both LEDs are solid green) will limit the intrusion of solid materials as small as dust-sized particles and will withstand exposure to splashing water from any direction.

Having said this, you must never expose the SPEAC® Detection Device to high-pressure water jets. Also, never allow the SPEAC® Detection Device to be submerged in any liquid while powered on. Contact Brain Sentinel® if the SPEAC® Detection Device or SPEAC® Laptop Base Station has been submerged. Do not attempt to use or service a SPEAC® Detection Device or SPEAC® Laptop Base Station that has been submerged.



### 3.5.3.3 Temperature of the Applied Parts

The temperature of the SPEAC<sup>®</sup> System's applied parts (those applied to the patient's biceps and arm) should never exceed 35°C or 95° F. In normal conditions, the temperature of the applied parts will approach the skin temperature of the patient. If the surface temperature of any applied part is hot when touched, immediately detach the SPEAC<sup>®</sup> Detection Device and turn it off and contact Brain Sentinel<sup>®</sup>.

## 3.5.4 Safe Usage of the SPEAC<sup>®</sup> System While Charging or During Configuration

### 3.5.4.1 Electro-Static Discharge Shock

When the SPEAC<sup>®</sup> Detection Device is detached from the Electrode patch, or the USB connector and the three electrode connections are accessible to the patient and/or operator, the basic safety of the SPEAC<sup>®</sup> Detection Device is the same as when it is attached to the Electrode.

Typically, the SPEAC<sup>®</sup> Detection Device will be connected to the SPEAC<sup>®</sup> Laptop Base Station for charging when it is not in the "Monitor Mode" (both LEDs are solid green). Charging can only be done by connecting the SPEAC<sup>®</sup> Detection Device to the SPEAC<sup>®</sup> Laptop Base Station with the USB cable provided. When the SPEAC<sup>®</sup> Detection Device is connected to the SPEAC<sup>®</sup> Laptop Base Station for charging, the required isolation for safety is maintained because the AC Adapter and SPEAC<sup>®</sup> Laptop Base Station meet the requirements of Class II Medical Electrical Equipment.



### 3.5.4.2 Ingress Protection

The SPEAC<sup>®</sup> System meets the IP22 classification when the SPEAC<sup>®</sup> Detection Device is in the Charge Mode (when the USB door of the SPEAC<sup>®</sup> Detection Device is open and connected to the USB cable). Solid material as small dust sized particles will have limited intrusion to the interior of the SPEAC<sup>®</sup> Detection Device enclosure through the USB door. The USB connector and the electrode connections are accessible and the SPEAC<sup>®</sup> Detection Device enclosure will only limit the intrusion of water to falling drops and light sprays. When the SPEAC<sup>®</sup> Detection Device is in the Charge/Configuration mode, position the SPEAC<sup>®</sup> Detection Device with the front surface facing up. This will restrict any liquid from accumulating on the rear surface near the USB connector and the electrode connections.

The SPEAC<sup>®</sup> Detection Device meets the IP47 classification when the SPEAC<sup>®</sup> Detection Device is in "Monitor Mode" (USB Door closed). However, if the SPEAC<sup>®</sup> Detection Device is submerged, it will be at risk of taking in water, permanently damaging the SPEAC<sup>®</sup> Detection Device and preventing it from being able to monitor for GTC seizures. Further, while the SPEAC<sup>®</sup> Detection Device is submerged, it cannot monitor or alarm for GTC seizures.

### 3.5.4.3 Temperature of the SPEAC<sup>®</sup> Detection Device, Laptop Base Station and AC Adapter

The parts of the SPEAC<sup>®</sup> Detection Device in the Charge/Configuration Mode are not Applied Parts. In normal room temperature and conditions, the temperature of the SPEAC<sup>®</sup> Detection Device, SPEAC<sup>®</sup> Laptop Base Station, and AC adapter should never exceed 35°C.

If the surface temperature of any SPEAC<sup>®</sup> Detection Device is hot to the touch, immediately detach the SPEAC<sup>®</sup> Detection Device from the SPEAC<sup>®</sup> Laptop Base Station, turn it off and contact Brain Sentinel<sup>®</sup>.

If the surface temperature of the AC Adapter or the SPEAC<sup>®</sup> Laptop Base Station is hot to the touch, immediately disconnect the power inlet cord to the AC Adapter, disconnect it from the SPEAC<sup>®</sup> Laptop Base Station, and shut it down.

## 4. Using the SPEAC® System



*Figure 4A. The SPEAC® Detection Device on the Biceps of the Arm*

Before using the SPEAC® System for the first time, please read through all of Section 4 so you can better understand how to use the SPEAC® System. The order in which you complete the tasks is important. Here is the summary of the steps you will complete. The rest of this section contains the details for completing each step.

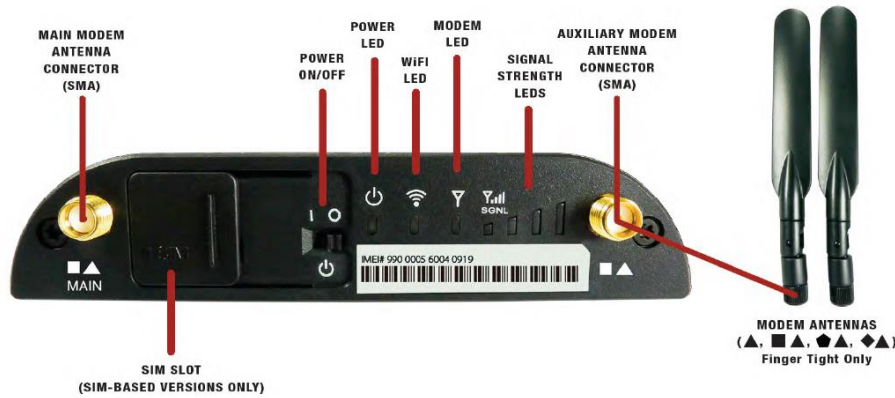
1. Turn on the CradlePoint Wireless Router
2. Turn on the SPEAC® Laptop Base Station
3. Review the Setup Wizard on the SPEAC® Laptop Base Station
4. Place the SPEAC® Detection Device on your biceps and turn on
5. Perform the Electrode Setup
6. Be monitored within your home Wi-Fi zone
7. Change out the SPEAC® Detection Device and Electrode Patch every 24 hours

### 4.1 Placing the SPEAC® System to Begin Being Monitored

For proper functioning of the SPEAC® System, complete the setup process in the order listed below.

#### 4.1.1 Turn On the CradlePoint Router

1. Attach the WiFi and modem antennas.



**Figure 4B. CradlePoint Wireless Router Buttons and Lights**

2. Plug the outlet cord into the input on the rear of the CradlePoint Wireless Router.



**Figure 4C. CradlePoint AC Adaptor**

3. Plug the cord of the CradlePoint Wireless Router into the wall outlet.
4. Press the Power ON/OFF switch located next to the power input connector on the back of the CradlePoint Wireless Router.
5. Before powering ON the SPEAC® Laptop Base Station (step 3 in the next section), wait until the Wi-Fi LED indicator is blue – this is your signal that the router has successfully connected to the internet.
6. If you cannot see that the CradlePoint router has connected successfully to the internet, contact Brain Sentinel’s Customer Service for assistance.

#### 4.1.2 Turn On the SPEAC® Laptop Base Station

1. Plug the outlet cord of the AC adaptor into the input on the left side of the SPEAC® Laptop Base Station.
2. Plug the inlet cord into the AC adaptor and then into the wall outlet.
3. Turn on the SPEAC® Laptop Base Station by pressing the power button on the upper left corner of the keyboard.

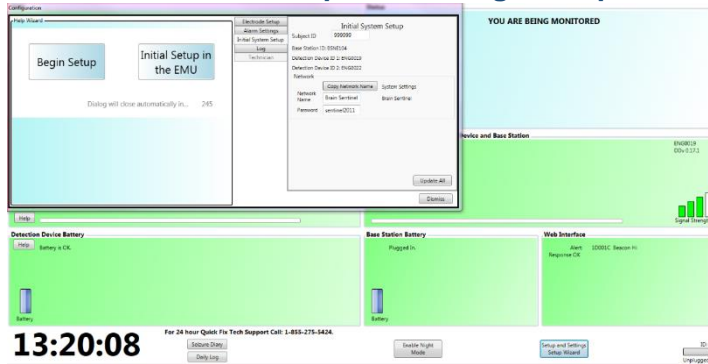
4. Check the bottom Windows bar to see if the SPEAC® Laptop Base Station is connected to the



Wi-Fi. You should see a series of bars like in this screenshot.

5. The SPEAC® BaseStationApp, will start automatically after Windows boots up.
6. If the “POST Error” appears, select OK. Close the SPEAC® BaseStationApp and reopen it. If the “POST Error” appears again, contact Brain Sentinel to help troubleshoot this issue. Leaving a POST Error unresolved means that the wireless connections are not functioning properly and may leave you unmonitored for generalized tonic-clonic seizures.

### 4.1.3 Launch the “Setup and Settings Setup Wizard”



In the SPEAC® BaseStationApp, there is a button on the bottom right called “Setup and Settings Setup Wizard”. Click this button to begin playing the Configuration Wizard videos. These Wizard videos provide instructions on the proper configuration, calibration and use of the SPEAC® System.

**Figure 4D. The Setup and Settings Wizard**

The videos included in the Wizard are as follows:

- Welcome to your SPEAC® System
- Your Biceps, a Critical Communicator to Help You “SPEAC®”
- Preparing Your Biceps for Placement
- Attaching the Electrode to the Detection Device
- Placing the Device
- Turning on the Detection Device
- Electrode Setup
- The Arm Strap
- Changing the Device

If you forget something you can always go back to the Wizard later to see the videos again.

Sections 4.1.4 – 4.1.6 of this User Manual are included for you to use along with the Wizard videos.

### 4.1.4 The Importance of Your Biceps

Before using one of the pre-charged Detection Devices, you need to prepare your biceps. Your SPEAC® Detection Device works by continuously sensing and monitoring your surface electromyography (sEMG) signals. The Detection Device reads and records 1,000 sEMG samples every second. Then our SparkSense™ diagnostic algorithm analyzes those samples looking for tonic-clonic muscle activity that is indicative of generalized tonic-clonic seizures. The continuous analysis and storage of your real-time EMG activity is why we say that the SPEAC® System is ready to speak for you during a seizure, and again when you visit your doctor.



**Figure 4E. The Setup and Settings Wizard**

The only place for the SPEAC® Detection Device is on your biceps, specifically what is known as “the belly of the biceps” as seen in Figure 4.C. To find it, flex your elbow. The belly of the biceps is the thickest part of the muscle, about halfway between your shoulder and elbow. When properly placed, the electrodes on the Detection Device are recording your biceps’ activity 1,000 times a second. This helps the SPEAC® System stay on top of changes from your normal EMG patterns that might be indicative of a generalized tonic-clonic seizure.

The electrode patch should never be applied to irritated or broken skin. Please consult your physician if skin irritation should occur with use of this product.

#### **4.1.5 Attaching the Detection Device to Your Biceps**

Before using one of the pre-charged SPEAC® Detection Devices, you need to prepare your biceps. Your doctor may recommend whether you should place the Detection Device on your right or left biceps, or if either is acceptable.

You must first prepare your skin over your biceps before placing the SPEAC® Detection Device on it. To do so, you need to remove the naturally occurring oils on the surface of your skin to ensure that the electrode patch stays properly attached to your arm.

Find the wipes that came with your SPEAC® System and gently wipe the skin on top of your biceps. Do not use alcohol to clean your skin. Alcohol will react with the electrode gel and cause severe skin irritation.



**Figure 4F. Electrode Patch placement in the SPEAC® Detection Device sockets**

Once your skin is prepared, take an electrode patch from the supply you were sent. Turn the Detection Device over and secure all three snaps in the sockets. You’ll hear a small click when you put them in. Don’t turn on the Detection Device just yet or else the alarm will sound.



**Figure 4G. Moistening the Electrode Gels**

Once the electrode patch is snapped in correctly, remove the plastic covering. This will expose the adhesive. Take a cotton swab, dip it in water, and moisten the gel on each of the three grey electrode contacts, twice.

Now take the SPEAC<sup>®</sup> Detection Device and place it on your biceps, holding it firmly against your biceps for five (5) seconds. As mentioned before you must place it on the belly of the biceps – not on the side, and not above or below the belly of the biceps. Remember, the electrode patch should never be applied to irritated or broken skin.

The adhesive on the electrode patch will generally last up to 24 hours. If the contact with your skin becomes poor, the Loose Electrode alarm will sound. Remember that you are still not being monitored, but you soon will be soon after you calibrate the electrode.

Now, check the time and take note. The electrode gel needs 5 minutes to absorb the water you just applied to it so the Detection Device can properly monitor you. So, start a five minute countdown as soon as you have the SPEAC<sup>®</sup> Detection Device properly placed on your biceps.

#### 4.1.6 The Electrode Setup Process

In order for the surface electrodes to work properly, you must calibrate every new electrode patch you place on the SPEAC<sup>®</sup> Detection Device. Not doing so could result in you not being monitored properly. Before proceeding, make sure that

1. The SPEAC<sup>®</sup> Detection Device is OFF
2. The CradlePoint Wireless Router is turned ON
3. The SPEAC<sup>®</sup> Detection Device is adhered properly to your biceps

Now the equipment is ready for you to move ahead to set up the electrodes.



**Figure 4H. SPEAC<sup>®</sup> Detection Device ON/OFF Button**

Turn on the SPEAC<sup>®</sup> Detection Device by pressing the small button located on the top, as seen in Figure 4H.

When you press it, you'll hear a sound. A series of lights will flash and after a moment, both lights will turn green to indicate that it is connected wirelessly to the SPEAC<sup>®</sup> Laptop Base Station. If the lights don't turn green, double-check that the SPEAC<sup>®</sup> Laptop Base Station is connected to the CradlePoint Wireless Router.

*Do not proceed past this step until both lights on your Detection Device are green. If you need immediate assistance, please call Brain Sentinel<sup>®</sup> at 1-855-275-5424.*

The final step in getting your SPEAC<sup>®</sup> Detection Device ready for use is setting up the electrode. This is part of helping the SPEAC<sup>®</sup> System know the difference between a generalized tonic-clonic seizure and your normal activity. It also helps calibrate the SPEAC<sup>®</sup> Detection Device to background electrical noise.

Once five (5) minutes have passed (as indicated in Section 4.1.4) for the gel to absorb the water, relax the arm that has the SPEAC<sup>®</sup> Detection Device on it. During this setup, don't flex your biceps muscles. It's best to have your arm simply hanging at your side. On the SPEAC<sup>®</sup> Laptop Base Station screen you will see a button for the Electrode Setup. Press it, then click "Begin Electrode Setup" and for the next 10 seconds, the SPEAC<sup>®</sup> System will be taking your EMG measurements. You can see the status on the screen while the three electrodes are automatically setup for you.

Correct EMG analysis relies on the characteristics of the electrode/skin interface. When a new electrode patch is applied to the patient, these characteristics must be measured to make certain the proper compensations are provided. These measurements are required at each electrode change. During this procedure, the patient's EMG levels at rest will be measured.

When you see the "Electrode Setup is Complete" message, click the "Dismiss" button. You are now being monitored for generalized tonic-clonic seizure activity. Remember the electrode setup process must be completed whenever you apply a new electrode.

#### 4.1.7 Electrode Patch Adhesive and Your Skin

Ongoing use of the electrode patch may irritate your skin. To minimize this, it is important to take care when applying and removing the electrode patch. Here are a few tips.

##### Tips for applying the adhesive electrode patch

- Apply an alcohol-free skin protectant to protect skin prior to applying the Adhesive Patch. (Please contact Brain Sentinel, Inc. for a list of skin protectants)
- Allow all skin protectants to dry thoroughly before applying the Adhesive Patch

##### Recommended procedures for removing Adhesive Patch

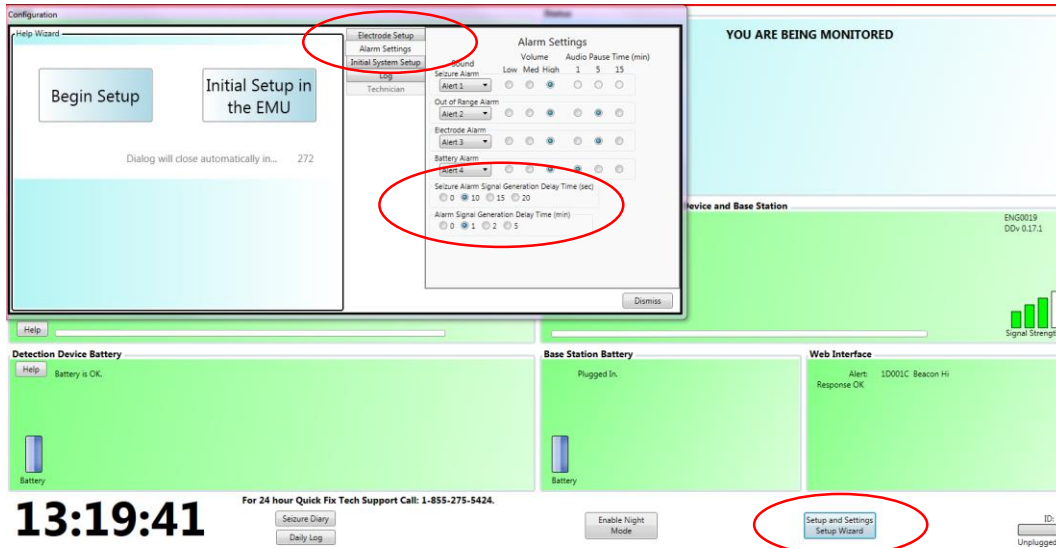
- Loosen the edges of the Adhesive Patch
- With the fingers of the opposite hand, push the skin down and away from the adhesive electrode patch, then...
- Peel the adhesive electrode patch low and slow back over itself, keeping it horizontal and close to the skin surface
- As the adhesive electrode patch is removed, continue moving fingers of the opposite hand as necessary to support newly exposed skin
- You may want to loosen the adhesive bond by slow and careful removal of the adhesive electrode patch using water-soaked cotton balls to continuously wet the adhesive-skin interface
- Use proper removal technique to avoid skin injury. Injury can be caused by quick removal of the Adhesive Patch at a high angle (perpendicular to the skin). Injury can also be caused by not holding the skin at the peel line when removing the Adhesive Patch.

#### 4.2 Configure the SPEAC<sup>®</sup> System Alarm Settings

The SPEAC<sup>®</sup> System has both Seizure Alarms and System Operational Alarms. Through the SPEAC<sup>®</sup> BaseStationApp, you can configure

- Alarm tones
- Alarm tone volumes
- Silence times for Operational Alarms (similar to a Snooze button on an alarm clock)
- Alarm grace time periods (how long before a seizure alarm goes off once detected)

The Alarm Settings are accessed from the Configuration window. Select the "Setup and Settings Setup Wizard" button in the bottom right of the application window and then select the Alert Settings tab to configure the tones generated for the alarms, and the silence and grace time periods.



**Figure 4G. SPEAC® System Alert Settings**

The default settings for the alarm settings are shown above. These will be configured by the physician’s office and should not be changed.

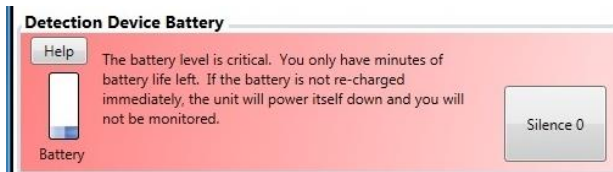
**4.2.1. Alarm Tones and Volume Levels**

There are five alarm tones available in the SPEAC® System. The default selections will result in unique tones for each of the alarm conditions and should not be changed. The default volume levels are set to “High” for all alarm conditions. But “Medium” and “Low” options are available. If you mute the alarm tones, the SPEAC® System will automatically turn them back on to medium level.

**4.2.2. Silence Time**

There are three (3) Operational Alarms that will go off if something is preventing the SPEAC® System from working properly. These alarms are the

- “Electrode” which sounds when the electrode patch is not adhered properly to the skin
- “Battery” which sounds when the rechargeable battery is critically low and needs to be recharged
- “Out of Range” which sounds when the SPEAC® Detection Device is outside of the Wi-Fi coverage zone and cannot connect to the rest of the SPEAC® System



**Figure 4I. Example of Operational Alarm with Silence Button on the SPEAC® Laptop Base Station**

You have the option to “Silence” these alarms temporarily when they go off. However, the only way to permanently turn these alarms off is to resolve the underlying cause that set them off. For these alarms, the resolution for each is

- “Electrode”: Adhere the electrode patch properly to the patient’s skin, which should be on the belly of the biceps. This may involve changing the electrode patch for a new one and/or putting on the SPEAC® Arm Strap.
- “Battery”: Change out the battery for the charged one attached to the SPEAC® Laptop Base Station



- “Out of Range”: Return to the covered Wi-Fi zone. It is important to know where these boundaries are in your home.

Three Silence Lag Time options (1, 5 and 15 minutes), are available for these Operational Alarms. In addition, the SPEAC® Laptop Base Station will also visually display and sound for these alarms. When this happens, a “Silence” button will appear, allowing you to silence the alarm until you can resolve the issue and continue being monitored. **Note:** The SPEAC® Detection Device Critical Battery Alarm cannot be silenced or snoozed, and the alarm sound will start as soon as the alarm condition is received by the Base Station.

#### 4.2.3. Seizure Alarm Grace Time

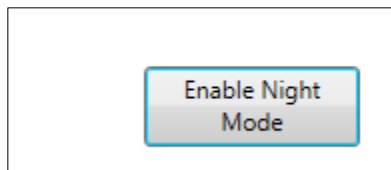
The “Seizure Grace Time” is the delay between when a Seizure Alarm is received by the SPEAC® Laptop Base Station and when the Seizure Alarm sound is generated. Select one of four Seizure Grace Time settings: 0, 10, 15, or 20 seconds.

#### 4.2.4. Operational Alert Grace Time

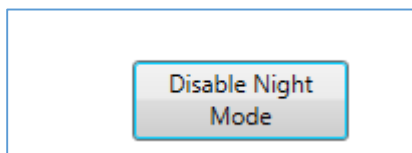
When a Loose Electrode or Wi-Fi connection Alarm is received by the SPEAC® Laptop Base Station, the alarm sound will be delayed by the time selected in the “Alarm Grace Time” column. Select one of four Alarm Grace Time settings: 0, 1, 2 or 5 minutes.

#### 4.2.5. Night Mode

In order to help you sleep soundly, you have the option to dim the LED lights on the SPEAC® Detection Device at night. Dimming the lights puts the SPEAC® Detection Device in “Night Mode”. This option is located at the bottom of SPEAC® BaseStationApp as shown below in Figure 4J.



Clicking the “Enable Night Mode” button will activate “Night Mode”, making the SPEAC® Detection Device LED light softer. This button will only appear when the “Night Mode” is disabled.



Clicking the “Disable Night Mode” button will bring back daylight mode, making the SPEAC® Detection Device LED operate at regular brightness. This button will only appear when the “Night Mode” is enabled.

**Figure 4J. Night Mode Controls on the SPEAC® Laptop Base Station**

### 4.3 Test the Wi-Fi Range of the SPEAC® Detection Device

In an open field environment the CradlePoint IBR600 series router can communicate with the SPEAC® Detection Device up to approximately 300ft. However, the range within a building or dwelling will vary based on their size, shape and type of building material. These differences in home construction can affect the safe and effective monitoring range for Generalized Tonic-Clonic Seizures. Upon first setup in a

new location, you should take the following steps to ensure your awareness of the monitoring range in each new environment.

Slowly walk away from the router, monitoring the Wi-Fi status LED, and perform the following

1. Go to commonly occupied areas of the home.
2. Walk the perimeters of each commonly used room.
3. Next, walk the perimeter of each floor.

**Note:** Not all routers will achieve the same range of communication, the previous steps should also be performed when using a different router or when changing to a new router.

#### 4.3.1. Troubleshooting Lost Wi-Fi Connections with the Detection Device

If the SPEAC® Detection Device has lost communication with the SPEAC® Laptop Base Station the Wi-Fi status LED will cease to illuminate green, and will begin to flash. If this happens, during any of the previous steps, you can do one of two things; note where the loss of connection takes place and avoid this area while being monitored for Generalized Tonic-Clonic Seizures, or contact Brain Sentinel® at 1-855-275-5424, to discuss your options regarding a Wi-Fi repeater installation to improve the communication distance.

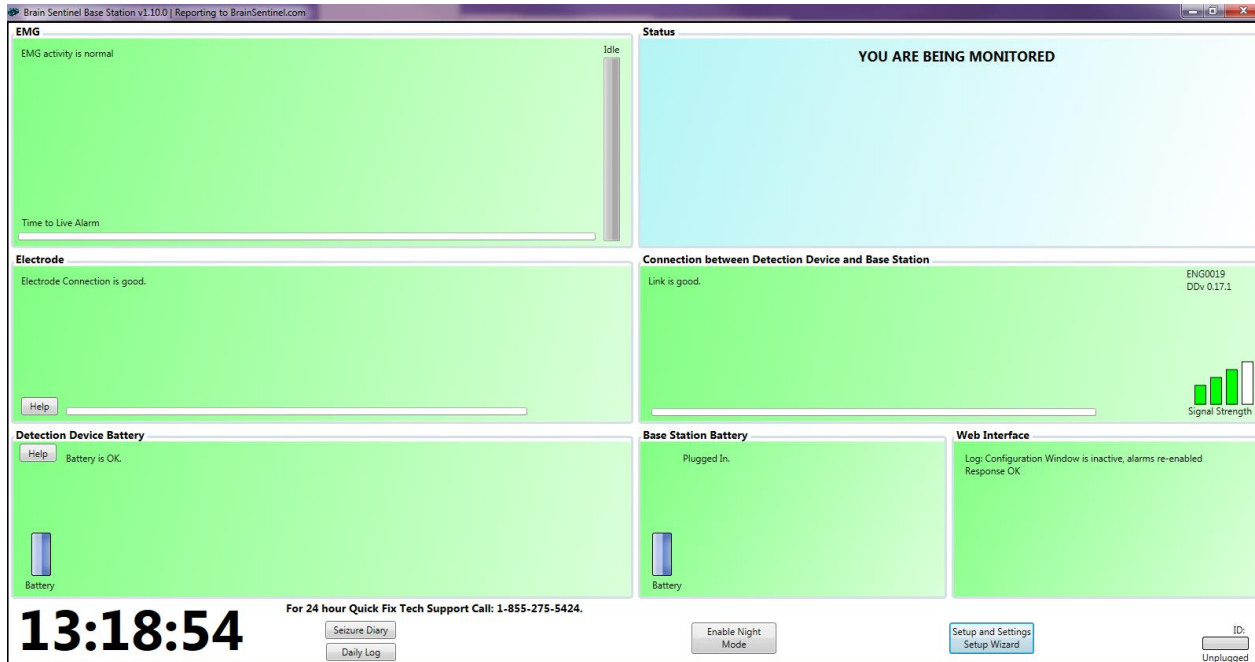
**Note:** A Wi-Fi repeater may not solve communication issues due to obstacles in your home.

#### 4.4 Understanding the SPEAC® Laptop Base Station Application, Indicators and Controls

The SPEAC® Laptop Base Station Application screen is composed of multiple tiles. Each one corresponds to a specific monitor to ensure that the SPEAC® System is working properly, that you are being monitored, and that the SPEAC® Detection Device is communicating with the SPEAC® Laptop Base Station whether or not a seizure is currently being detected.

This section defines and describes the stages each tile you will see and need to become familiar with when using the SPEAC® System:

- EMG Tile, See Section 4.4.1
- Status Tile, See Section 4.4.2
- Electrode Tile, See Section 4.4.3
- Connection Tile, See Section 4.4.4
- DD Battery Tile, See Section 4.4.5
- Base Station Battery Tile, See Section 4.4.6
- Web Interface Tile, See Section 4.4.7
- General Access Tile, See Section 4.4.8
- Seizure Diary, See Section 4.4.9
- Daily Log, See Section 4.4.10



**Figure 4K. SPEAC® BaseStationApp Main Window**

The indicators (visual and audible), and controls are arranged on the SPEAC® BaseStationApp main window in an array of tiles. The following sections describe the function of each tile. Software and firmware version are displayed in the banner and in the Detection Device Communication tile.

**NOTE:** Indicators and controls are not always visible. The following sections describe the detailed functions of each tile.

**Table 4A. SPEAC® BaseStationApp Color Indicators**

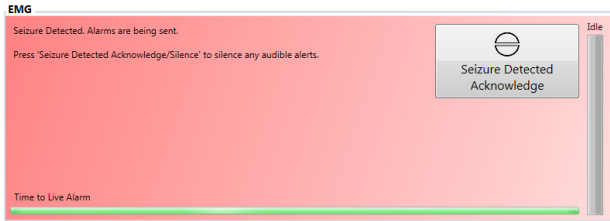
Tile Background Color	Event Type	Description	Indicators and controls
Green	Normal	Monitored activity within normal operating parameters	Visible when needed
Blue	Notice	Monitoring activities have fallen out of normal operating parameters and status is unknown. Unless action is taken, a warning will be issued.	Visible when needed
Yellow	Warning or Advisory	Warn the local and remote users that action needs to be taken.	Visible when needed
Red	Warning or Advisory	Warn the local and remote users that action needs to be taken immediately.	Visible when needed

#### 4.4.1 EMG Tile

The EMG tile is on the top left of the SPEAC® BaseStationApp main window and contains both indication and control functions. The tile can be green, red or blue and contains a progress bar showing the time until the alarm is live. It is called the “Time to Live Alarm”. It is also an indication of the relative EMG signal.



**GREEN State:** When the EMG Tile is green, the patient’s EMG is normal. In the GREEN state, the “Time to Live Alarm” indicator is inactive (i.e. progress bar is all grey).

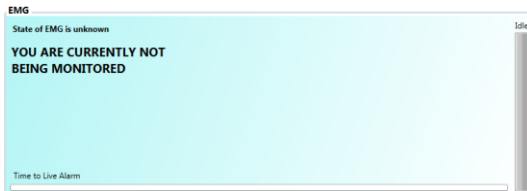


**RED State:** The EMG Tile will turn red when a GTC seizure alarm condition is received from the SPEAC® Detection Device. If a seizure alarm condition has been received, the “Seizure Detected Acknowledge/Silence” control button will appear in the tile, and the Time to Live Alarm indicator (Grace Time) will show the time remaining until the alarm

sounds.

If the Acknowledge/Silence control button is not selected before the Time to Live Alarm expires, an audible alarm will be generated and tile will flash red.

- Selecting the Acknowledge/Silence button will silence the audio alarm for 5 minutes or until the GTC Seizure condition has ended.
- If the GTC seizure condition persists, the tile will continue to flash red, and the alarm will sound again after 5 minutes.
- The EMG tile will return the GREEN State when the Acknowledge/Silence button is selected and the GTC seizure condition has ended.



**BLUE State:** If the state of the EMG signal is unknown, the EMG tile will turn blue and a status message will be displayed. The LED will be blinking yellow and the Seizure Alarm sound will be heard. Typically this is an indication of a loose electrode. See Electrode Tile (4.4.3) for details.

The same message will appear if the communication link between the SPEAC® Detection Device and the SPEAC® Laptop Base Station is lost or if the communication link between the SPEAC® Laptop Base Station and the web is lost.

#### 4.4.2 Status Tile

The Status Tile is on the top right of the SPEAC® BaseStationApp main window and contains both indication and control functions.



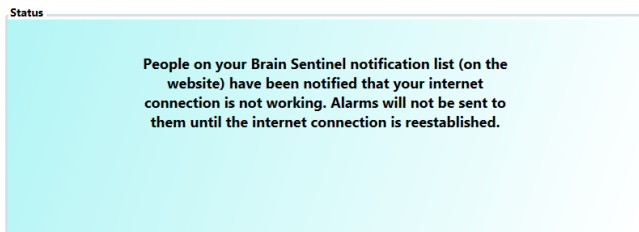
**BLUE State:** Indicates all functions of the system are normal and the patient is being monitored.

The status tile will display the message, “YOU ARE BEING MONITORED” if the system is functioning.

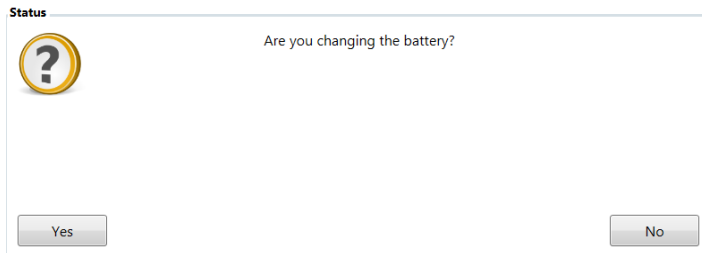


If any part of the system is not functioning properly or as expected to maintain monitoring, the Status tile will display the corresponding message.

While a GTC Seizure is being detected, this message will be shown on the Status tile.



**Web Connection Lost Status message.** If you see this message, your internet connection is not working properly. Correct the issue immediately. Call Brain Sentinel for assistance if needed.



**Decision Input Popup:** If user input is required, a question will be displayed in the status tile. The answers are used to direct the user to the appropriate help wizard.

The example at left will be displayed when the EMG signal is not within the expected limits indicating the electrode patch has

been disconnected from the skin.



**Wizard Display State:** Wizards will be displayed in the status tile based on the outcome of the decision icon and when Help buttons are selected in Electrode Tile or Detection Device Battery Tile.

### 4.4.3 Electrode Tile

The “Electrode Tile” is located on the left center of the main SPEAC® BaseStationApp window and contains both indication and control functions. The Electrode tile contains a Help button. When the Help button is selected, a pop-up window will be displayed in the Status tile.



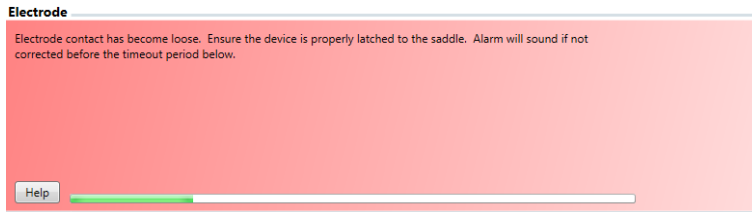
**GREEN State:** The Electrode Tile will be green when the quality of the contact of the electrode to patient’s skin is within the expected parameters to monitor the EMG signal.

The progress bar is inactive in this state. If the quality of the electrode to patient contact does not meet the expected limits, the tile will turn blue.



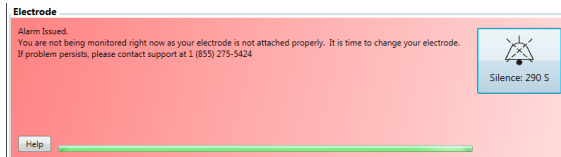
**BLUE State:** When the SPEAC® Laptop Base Station cannot determine the state of the contact between the patient and the electrodes, the Electrode Tile will be blue. A message indicating the status will be displayed as shown at left.

Typically this indicates that the communication link between the SPEAC® Detection Device and the SPEAC® Laptop Base Station has been lost and the SPEAC® Detection Device’s status has not been received by the SPEAC® Laptop Base Station. The message: “Electrode is unknown” will be displayed when the connection between the SPEAC® Detection Device and the SPEAC® Laptop Base Station is lost.



**RED State:** When the quality of the contact between the patient and the electrodes is substandard, the Electrode Tile will turn red and the progress bar will start advancing. The “Silence” button will be shown and start to count down for 300 seconds/5

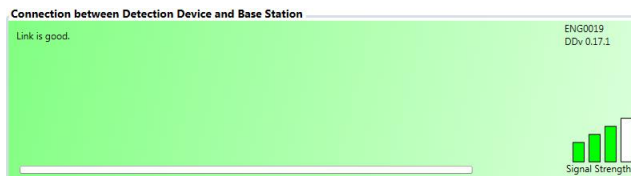
minutes.



Selecting the “Silence” button will mute the audible alarm. If the electrode/patient contact does not return to normal before the Silence timer (300 sec) expires, the Electrode tile will blink RED and audible alarm will restart.

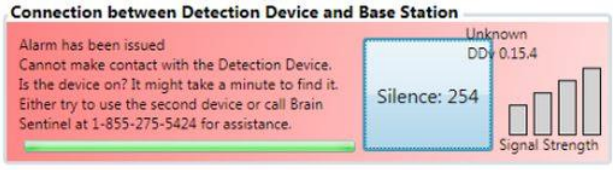
#### 4.4.4 Connection Tile (Connection Between the SPEAC® Detection Device and the SPEAC® Laptop Base Station)

The Connection Between Detection Device and Base Station Tile is located on the right center of the main SPEAC® BaseStationApp window. It contains both indication and control functions. Depending on the state of the Wi-Fi link between the SPEAC® Laptop Base Station and Detection Device, the Wi-Fi tile can contain both indication and control functions.



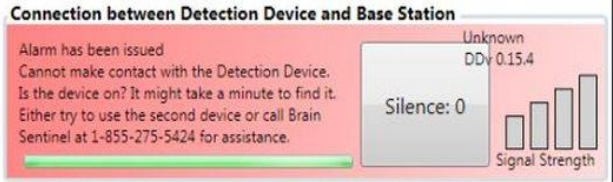
**GREEN State:** A satisfactory Wi-Fi link exists between the SPEAC® Detection Device and SPEAC® Laptop Base Station. The SPEAC® Detection Device serial number and FW version are displayed in the upper right corner of the tile. The relative signal strength of the Wi-Fi network

as seen by SPEAC® Detection Device is displayed in the lower right corner. The progress bar at the bottom of the tile will be blank as long as the tile is green.

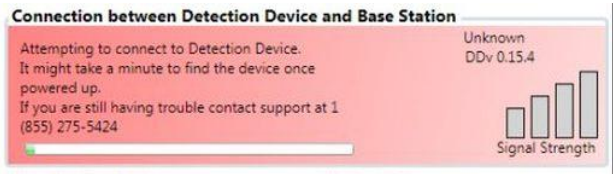


**RED State:** If the link between the SPEAC® Detection Device and the SPEAC® Laptop Base Station is lost, the Wi-Fi tile will turn red and the progress bar will begin counting down. The Silence button with timer will be shown. Selecting the Silence button will silence the audible alarm for the

out-of-range-silence time.



The out-of-range-silence delay expires according to the delay settings set during the setup of the SPEAC® System. Then the Wi-Fi tile will transition to the blinking RED state and an audible alarm will be generated.



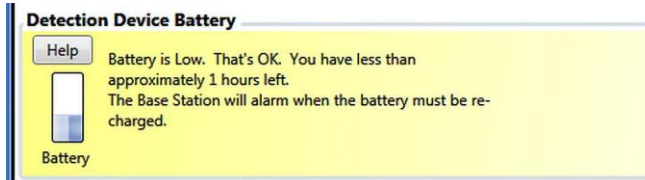
The Wi-Fi tile will remain in the RED state until the connection between the SPEAC® Detection Device and SPEAC® Laptop Base Station is restored.

#### 4.4.5 Detection Device Battery Tile

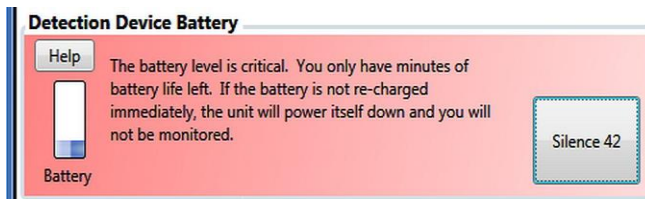
The “Detection Device Battery” tile is located on the bottom left the main SPEAC® BaseStationApp window. It contains the SPEAC® Detection Device battery status indications.



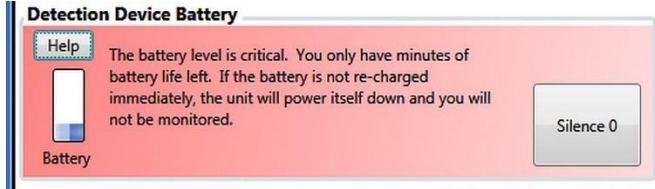
**GREEN State:** The SPEAC® Detection Device is communicating with the SPEAC® Laptop Base Station and has sufficient battery life.



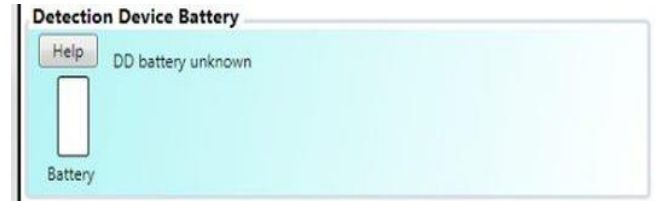
**YELLOW State:** The SPEAC® Detection Device is communicating with the SPEAC® Laptop Base Station and the battery is nearing critical status while the battery has less than 2 hours left.



**RED State:** When the Detection Device battery is at a critical level, the tile will flash red and an audible alarm will be generated. In addition, a wizard will start in the Status tile providing instructions on how to charge the SPEAC® Detection Device.



Follow the instructions provided in the Status tile.



**BLUE State:** When the SPEAC® Laptop Base Station cannot determine the state of the battery in the SPEAC® Detection Device that is monitoring the patient, the SPEAC® Detection Device’s Battery tile will be blue. A message indicating the status will be displayed.

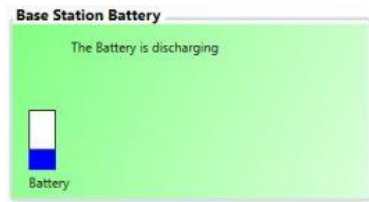
Typically when this occurs the communication link between the SPEAC® Detection Device and the SPEAC® Laptop Base Station has been lost and the SPEAC® Laptop Base Station cannot receive the SPEAC® Detection Device’s status.

**4.4.6 SPEAC® Laptop Base Station Battery Tile**

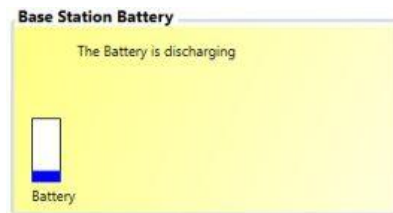
The **Base Station Battery** tile is located on the center right of the main SPEAC® BaseStationApp window. It indicates the status of the SPEAC® Laptop Base Station battery.



**GREEN State:** The SPEAC® Laptop Base Station is plugged in and the battery is charged.



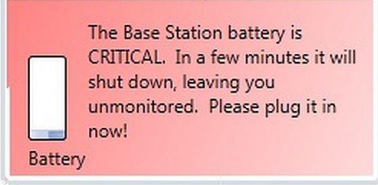
**GREEN State:** Unplugging the SPEAC® Laptop Base Station’s AC Adaptor from the wall will not automatically generate a red tile. As long as there is sufficient charge left in the SPEAC® Laptop Base Station battery, the status tile will remain green.



**YELLOW State:** The SPEAC® Laptop Base Station is not plugged in and is powered by the internal battery. The battery gauge will indicate the relative capacity remaining in the battery.  
Reconnect the AC Adapter as soon as possible.



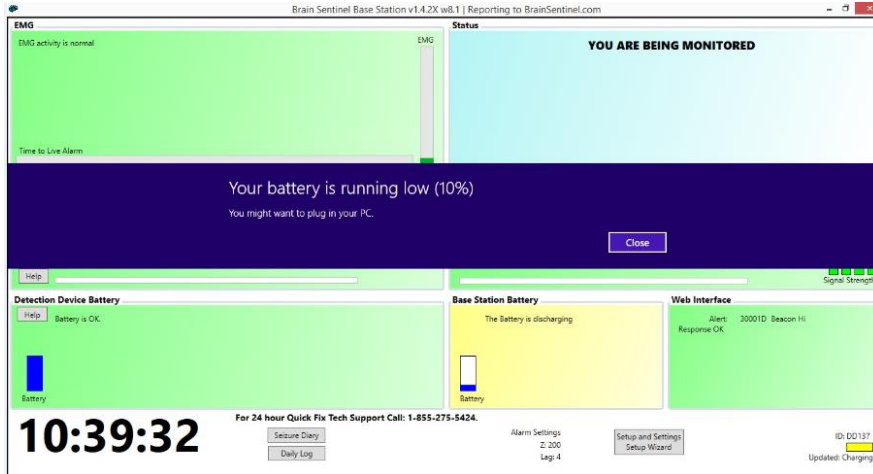
**Base Station Battery**



The Base Station battery is **CRITICAL**. In a few minutes it will shut down, leaving you unmonitored. Please plug it in now!

Battery

**RED State:** The SPEAC® Laptop Base Station is not plugged in and the battery capacity is at a critical level. Only a few minutes remain before the SPEAC® Laptop Base Station will shut down and remote monitoring will be unavailable. Reconnect the AC Adapter as soon as possible.

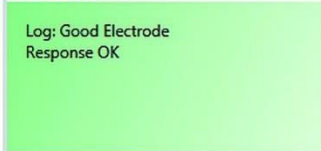


In addition, the SPEAC® Laptop Base Station (BSN) operating system, Windows 8.1, will show a message "Your battery is running low" while the BSN battery is running low.

**4.4.7 Web Interface Tile**

This tile shows the status of the link with the external Brain Sentinel® web server.

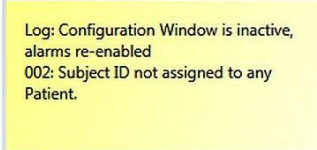
**Web Interface**



Log: Good Electrode Response OK

**GREEN State:** Remote alarm and monitoring functionality is fully operational.

**Web Interface**

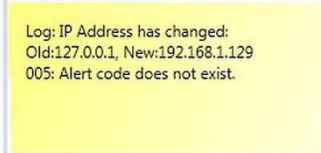


Log: Configuration Window is inactive, alarms re-enabled  
002: Subject ID not assigned to any Patient.

**YELLOW State:** Multiple messages will appear in the Web Interface tile when it is in the Yellow state.

**NOTE:** While in a yellow state, Seizure and Operational alarms may not be received by the Brain Sentinel® server.

**Web Interface**



Log: IP Address has changed:  
Old:127.0.0.1, New:192.168.1.129  
005: Alert code does not exist.

**Note:** This IP address window is only for troubleshooting while the SPEAC® Detection Device and/or SPEAC® Laptop Base Station are not on the correct Wi-Fi network.

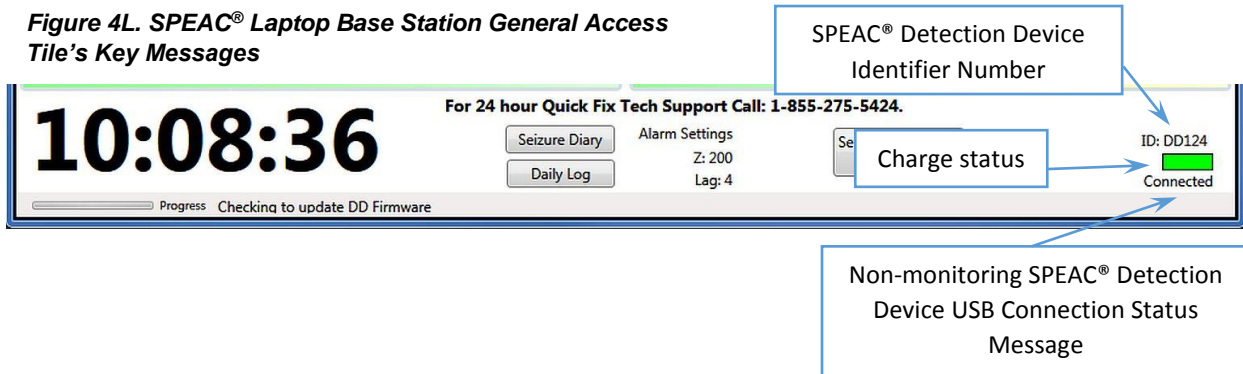


**RED State:** No external communication can take place with the Brain Sentinel® web server. Either the internet connection is down or the Brain Sentinel® server is down. For assistance, contact Brain Sentinel® at 1-855-275-5424.

#### 4.4.8 General Access Tile

The General Access Tile is located at the bottom of the SPEAC® BaseStationApp window. This tile contains both indication and control functions. The time of day is always displayed as well as the Tech Support phone number. The charging status of the SPEAC® Detection Device connected to the SPEAC® Laptop Base Station’s USB port is displayed in the lower right corner of this tile. The state of the spare SPEAC® Detection Device is displayed in the lower right corner of the General Access tile. If the non-monitoring SPEAC® Detection Device is connected to the USB port on the SPEAC® Laptop Base Station, the identification number of the SPEAC® Detection Device is displayed above the “Charge Status Indicator” and a message indicating if the non-monitoring SPEAC® Detection Device is connected or disconnected. The “Charge Status Indicator” will be yellow when the Detection Device is connected and charging the battery. The “Charge Status Indicator” will be green when the battery is fully charged. If the SPEAC® Detection Device is not connected, the “Charge Status Indicator” will be grey, the identification number will be blank, and the message will be “Unplugged”

**Figure 4L. SPEAC® Laptop Base Station General Access Tile’s Key Messages**



#### 4.4.9 Seizure Diary

Selecting the Seizure Diary button activates an electronic form. The operator/patient can enter details related to his or her seizures. Complete the form as instructed in the window

#### 4.4.10 Daily Log

Selecting the Diary Log button activates a dialog so the operator/patient can enter details related to the patient’s daily routine. Complete the form as instructed in the window.

## 4.5 Understanding the SPEAC® System Alarms, Alerts and Messages

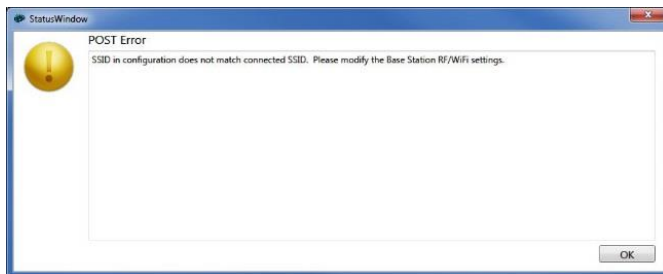
### 4.5.1 SPEAC® System Alarms and Alerts

The audio sounds generated by the SPEAC® System fall into two categories: Seizure Alarms and System Operational Alarms. Familiarize yourself with the different types of alarms that exist in the SPEAC® System using the alarm priority matrix in Table 4B. .

**Table 4B. SPEAC® System Alarm Priority Matrix**

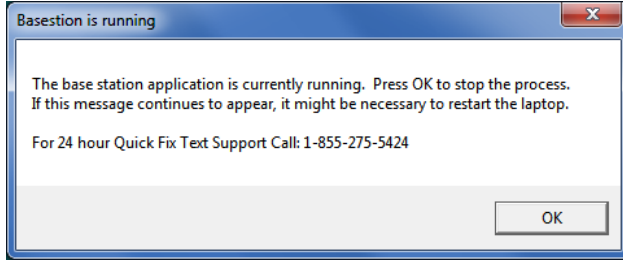
Alarm Type	Priority Level	Condition	Tile on SPEAC® Laptop Base Station	Tile Color	Audio?
Seizure	High	Seizure Detected	Seizure	Red	Yes
Seizure	High	Manual Seizure Activation	Seizure	Red	Yes
Seizure	High	Post Seizure no acknowledgement	Seizure	Red	Yes
Operational	High	Seizure Detected but no link to BSN	DD Connection	Red	Yes
Operational	High	Electrode Loose Connection	Electrode	Red	Yes
Operational	High	DD Battery Critical	DD Battery	Red	Yes
Operational	High	DD communication lost with BSN	DD Connection	Red	Yes
Operational	High	BSN Battery Critical	BSN Battery	Red	Yes
Operational	Medium	Lost Connection Initial attempts	DD Connection	Yellow	No

### 4.5.2 Laptop BaseStationApp System Messages



**“POST Error”:** The POST Error will be displayed when SPEAC® BaseStationApp has been configured to join a network different than the network to which the SPEAC® Laptop Base Station has joined. If you see this error, close the BaseStationApp and reopen it. This should resolve it. If the problem persists, call Brain Sentinel’s Customer and Technical Support to resolve the issue. Leaving this problem

unresolved will result in your SPEAC® System not monitoring you.
















**“Base Station is running”:** This message may be shown while the user starts to run another “SPEAC® BaseStionApp” program while the existing program is not completely closed. Click OK to close window and the application will open automatically.

## 4.6 Understanding the SPEAC® System LED Lights and Indicators

### 4.6.1 Patient Connection and Wi-Fi Status at Startup

*Table 4C. SPEAC® System Alarm Priority Matrix*

Condition	Status (Wi-Fi) LED	Alarm (Electrode) LED	Speaker	Haptic	Message (SPEAC® System Detection Device to SPEAC® Laptop Base Station)	Notes
<b>Power On Self- Test (POST)</b>	 White	 White	Announce tone	3 bursts	None	1
<b>Power On Wi-Fi searching sequence</b>	 Yellow to  Purple to  Blue to  Green		None	None	None	2
<b>DD Application Failure</b>	 Red	 Red	None	None	None	3
<b>Battery Low</b>	 Blue Flash	 Purple Flash	None	None	Low Battery in Status	4
<b>Battery Critical</b>	 Blue Flash	 Red Flash	Critical Battery Alarm Tone	None	Critical Battery in Status	5









#### Special Notes:

- POST should take less than 5 seconds to complete. Both LEDs should be white unless battery is in a low condition during this time. If the LEDs display any other color at the end of the POST time, turn off the SPEAC® Detection Device and contact Brain Sentinel®.
- **NOTE 2:** The SPEAC® Detection Device goes through a sequence to find the Wi-Fi network generated by the CradlePoint Router and SPEAC® Laptop Base Station connection.
- **NOTE 3:** SPEAC® Detection Device cannot boot up and fails. Please call Brain Sentinel®. (Refer to contact information in Section 5)
- **NOTE 4:** The SPEAC® Detection Device Laptop Base Station continues monitoring the SPEAC® Detection Device battery status.
- **NOTE 5:** The SPEAC® Detection Device battery requires immediate re-charging. Within 5 minutes, you must swap the SPEAC® Detection Device with the spare (fully charged) SPEAC® Detection Device. If this condition is not remedied, the SPEAC® Detection Device will power off and monitoring will be discontinued.







#### 4.6.2 SPEAC® Detection Device LED's Patient Connection and Wi-Fi Statuses during Normal Operation

**Note:** Red row shows LED indication during Blind Mode.

**Table 4D. Patient Connection and Wi-Fi Status Summary**

Condition	Status (Wi-Fi) LED	Alarm (Electrode) LED	Speaker	Haptic	Message SPEAC® Detection Device -> SPEAC® Laptop Base Station	Notes
<b>Patient Status OK Wi-Fi-Connected</b>	 Green	 Green	None	None	None	Normal mode
<b>Manual GTC Seizure Alarm Activation</b>	 Red	 Red Flash	GTC Seizure Alarm Tone with long pulse	GTC Seizure Alarm vibration with long pulse	Manual GTC Seizure Alert at SPEAC® Laptop Base Station	
<b>Loose Electrode Alarm</b>	 Yellow Flash	 Red Flash	Electrode Alarm Tone	None	Electrode Message at SPEAC® Laptop Base Station	-
<b>GTC Seizure Warning (before Lag period)</b>	 Green	 Purple	None	None	None	-

<b>BLIND MODE</b> <b>GTC Seizure Warning</b> (before Lag period)	 Green	 Green	None	None	None	1
<b>GTC Seizure Alarm</b> (after Lag period)	 Red	 Red Flash	GTC Seizure Alarm Tone with short pulse	GTC Seizure Alarm vibration with short pulse	Alarm at SPEAC® Laptop Base Station	-
<b>BLIND MODE</b> <b>Seizure Alarm</b>	 Green	 Green	None	GTC Seizure Alarm vibration with short pulse	Alarm at SPEAC® Laptop Base Station	1
<b>GTC Seizure Alarm</b> (Wi-Wi link is down)	 Red Flash	 Red Flash	GTC Seizure Alarm Tone with short pulse	GTC Seizure Alarm vibration with short pulse	None (no link)	2
<b>BLIND MODE</b> <b>Seizure Alarm</b> (Wi-Fi link is down)	 Green	 Green	None	GTC Seizure Alert vibration with very short pulse	None (no link) Send seizure when link is reestablished	1
<b>Post-GTC Seizure and no acknowledgement</b>	 Red	 Red Flash	GTC Seizure Alarm Tone with long pulse	GTC Seizure Alarm vibration with long pulse	Alarm at SPEAC® Laptop Base Station	3
<b>BLIND MODE</b> <b>Post-GTC Seizure and no acknowledgement</b>	 Green	 Green	None	None	Alarm at SPEAC® Laptop Base Station	1
<b>Battery Low</b>	 Blue Flash	 Purple Flash	none	None	Low Battery in Status	2

<b>Battery Critical</b>	 Blue Flash	 Red Flash	Critical Battery Alarm Tone	None	Critical Battery in Status	3
<b>Lost Wi-Fi Connection</b>	 Purple Blip	 Red Flash	Wi-Fi Link Alarm	None	Web Interface Message at SPEAC® Laptop Base Station	-
<b>Wi-Fi lost SPEAC® Laptop Base Station connection</b>	 Blue Blip	 Red Flash	Wi-Fi Link Alarm	None	Web Interface Message at SPEAC® Laptop Base Station	-

- **NOTE 1:** Alarm moves to lowest internal priority allowing all other alerts to be active.
- **NOTE 2:** If the Wi-Fi Status LED remains off for more than 10 seconds, power off the Detection Device and contact Brain Sentinel®.
- **NOTE 3:** The seizure has ended, but no acknowledgment has been received from the SPEAC® Laptop Base Station. The SPEAC® Detection Device will stay in a post-GTC seizure state until this GTC Seizure Alarm is acknowledged by an operator at the SPEAC® Laptop Base Station, or cancelled by the patient, or a new GTC seizure is detected

#### 4.7 The SPEAC® Arm Strap



**Figure 4M. SPEAC® Arm Strap**

Once the SPEAC® Detection Device is secured to the patient using an Electrode Patch, the SPEAC® Arm Strap can be used.

1. See Figure 4M. Make sure the Velcro tab is on the outside.
2. Fit the SPEAC® Arm Strap over the front of the SPEAC® Detection Device.
3. Tighten the SPEAC® Detection Strap by pulling the long end through the loop, until the slack in the strap is removed. Secure in place with the Velcro tab.
4. Take care not to over tighten the strap, you should be able to gently insert one finger between your skin and the strap

If discoloration or swelling occurs, immediately remove the SPEAC® Arm Strap and seek medical attention with your prescribing physician if the condition persists.

## 4.8 Daily SPEAC® Detection Device Changes

### 4.8.1 Remove the SPEAC® Detection Device From Your Biceps

Now that the application is closed, carefully and gently remove the SPEAC® Detection Device from your biceps.

1. Loosen the Velcro on the SPEAC® Arm Strap, then slide it toward the elbow freeing it from the SPEAC® Detection Device.
2. Gently peel the electrode patch from the skin from the edge of the patch. A small amount of water may help dissolve the adhesive making it easier to remove.
3. Gently pull the Electrode Patch from the SPEAC® Detection Device and discard the patch as normal household waste.
4. End a monitoring session at the SPEAC® Laptop Base Station by clicking on the red “X” in the upper right corner of the application window. (Standard method to close a Windows application.) The Status tile will turn white while this condition is reported to the Brain Sentinel® website.
5. Ensure at least one SPEAC® Detection Device is connected to the SPEAC® Laptop Base Station using the USB cable so a fully charged SPEAC® Detection Device will be available when monitoring is again necessary.

### 4.8.2 Connect the SPEAC® Detection Device to the SPEAC® Laptop Base Station for Charging and Uploading

The SPEAC® Detection Device that is not being used in the “Monitor” mode should always be connected to the SPEAC® Laptop Base Station. When the SPEAC® Detection Device is connected to the SPEAC® Laptop Base Station, the SPEAC® Detection Device’s battery is charging, EMG data is being transferred and configuration data is being updated.

Before the SPEAC® Detection Device is connected to the SPEAC® Laptop Base Station, make sure the SPEAC® Detection Device is on. Then connect the USB cable that came with your System to the USB connector on the bottom of the SPEAC® Detection Device behind the USB protective door. Once connected to the SPEAC® Detection Device, connect the other end to a USB port on the SPEAC® Laptop Base Station.



**Figure 4N. Detection Device USB Door and USB connector**

1. Before connecting, always make sure that the “SPEAC® BaseStationApp” on the SPEAC® Laptop Base Station is running.
2. Slide the USB Door lock away from the front face of the SPEAC® Detection Device. See Figure 4N above.
3. Once the connection is made, the “SPEAC® BaseStationApp” will verify the configuration of the SPEAC® Detection Device and transfer the collected EMG data to the Brain Sentinel® secure cloud storage.
4. Even though the LEDs on the connected SPEAC® Detection Device will be off, charging will continue.



5. The additional SPEAC<sup>®</sup> Detection Device should always be connected to SPEAC<sup>®</sup> Laptop Base Station's USB for charging and transferring the collected EMG data. After the SPEAC<sup>®</sup> Detection Device is connected to the SPEAC<sup>®</sup> Laptop Base Station's USB port, both status LEDs will turn off.

## 4.9 Maintaining the SPEAC<sup>®</sup> System for Optimal Performance

The patient and other users are expected to perform the routine maintenance of the SPEAC<sup>®</sup> System described in the following sections.

The rechargeable internal battery of the SPEAC<sup>®</sup> Detection Device and the electrode sockets integrated into the SPEAC<sup>®</sup> Detection Device require scheduled service after 500 days of use. All other components of the SPEAC<sup>®</sup> Detection Device will be evaluated at this time.

Contact Brain Sentinel<sup>®</sup> to arrange for service of your SPEAC<sup>®</sup> System. See Section 5 for contact information.

### 4.9.1 Cleaning

All maintenance described below should only be performed while the Detection Device is NOT in use.

The exterior surfaces of the SPEAC<sup>®</sup> System can be cleaned with a soft clean cloth, a paper towel dampened with 70% Isopropyl alcohol or disinfecting wipes. Lightly rub the exterior surfaces of the SPEAC<sup>®</sup> components: SPEAC<sup>®</sup> Detection Device, SPEAC<sup>®</sup> Laptop Base Station, AC Adapter, and USB cable and power cord. Remove any standing alcohol with a dry cloth or paper towel.

Do not apply any liquid to the USB connector of the SPEAC<sup>®</sup> Detection Device.

### 4.9.2 Battery Maintenance

Maintaining the SPEAC<sup>®</sup> Detection Device batteries charged at all times is critical for their ongoing proper performance. Like most rechargeable batteries, the SPEAC<sup>®</sup> Detection Device battery should be charged at least once every 4-6 weeks or kept at 50% charged when not being used. Fully charged batteries discharge when they are left unused and will lose effectiveness if they are left fully discharged for longer than four (4) weeks. Maintaining their charge will prolong the life of the batteries.

Charge the battery after each monitoring session. When the battery is fully charged, the battery can supply power for a 24-hour monitoring session. The time to charge a fully discharged battery is less than 6 hours.

The internal rechargeable battery used in the SPEAC<sup>®</sup> Detection Device has a minimum of 500 charge-discharge cycles.

Temperature is a key factor in the battery's performance over its life. Never charge the SPEAC<sup>®</sup> Detection Device if the ambient temperature is below 32° F (0° C) or above 113° F (45° C). Operating (or discharge) temperature should not be below 0° F (-18° C) or above 113° F (45° C).

The rechargeable battery used in the SPEAC<sup>®</sup> Detection Device can only be replaced by authorized personnel from Brain Sentinel<sup>®</sup>.

If properly used and maintained, the expected service life of the battery will meet the three-year expected service life of the SPEAC<sup>®</sup> System.

### 4.9.3 Electrode Socket Maintenance



Prior to insertion of a new electrode patch into the Electrode Sockets, inspect each socket for discoloring spots. Clear any debris or foreign materials.

The force applied by the electrode retaining snap will eventually reduce during normal use. Tests have shown the snap is capable of effectively retaining the electrode beyond 500 cycles.

**Figure 4O. SPEAC®  
Detection Device Electrode  
Sockets**

### 4.9.4 SPEAC® Detection Device Enclosure/Case Maintenance



Inspect the exterior for cracks and the interface between the front and rear enclosure halves. See Figure 4.9.4.

If defects are found, do not use the SPEAC® Detection Device and immediately contact Brain Sentinel® for a replacement.

**Figure 4P. SPEAC® Detection  
Device Enclosure**

### 4.9.5 Electrode Patch Maintenance

Replacement of the electrode patch is required when the skin-to-electrode contact does not provide adequate EMG signal quality to the SPEAC® Detection Device's electrical connections. The SPEAC® Detection Device continually monitors whether the electrode-to-skin contact is adequate to detect generalized tonic-clonic seizure conditions. When it is inadequate, the SPEAC® Detection Device issues an alarm to the patient and operator.

The skin-to-electrode contact is maintained by the hydrogel applied to the electrodes and the adhesive that bonds the electrode patch to the patient's skin. Over time, the adhesive will degrade and the hydrogel will dry causing intermittent connection of the electrodes to the patient's skin causing an inadequate electrode-to-skin condition.

Dispose of the used electrode patch as regular household waste.

### 4.9.6 Expected Service Life

Expected service life of the SPEAC® System is three years.

## 5. Discontinuing Monitoring and Returning the SPEAC® System

When your prescribed time for monitoring ends, you must return the entire SPEAC® System to Brain Sentinel®. You have two options for returning

1. **Call Brain Sentinel® Customer Service** toll free at 1-855-275-5424 and tell the Customer Service Representative that you need to return your System. Brain Sentinel® will send you a package and a shipping label.
2. **Email Brain Sentinel®** at [info@BrainSentinel.com](mailto:info@BrainSentinel.com) – wordsmith this

Within three (3) business days of receiving the shipping materials, pack up and ship the SPEAC® System back to Brain Sentinel®.

## 6. About Brain Sentinel, Inc.

Brain Sentinel, Inc. is the manufacturer of the SPEAC® System. For technical or customer support, please contact the company toll free at 1-855-275-5424, or send an email to [info@brainsentinel.com](mailto:info@brainsentinel.com).

**Physical Address:**

Brain Sentinel, Inc.

8023 Vantage Dr.

Suite 216

San Antonio, Texas, 78230

**Telephone:** +1-855-275-5424

- Technical Support, Extension 1
- Clinical Study Support, Extension 2
- Customer Service, Extension 3

**Website:** BrainSentinel.com






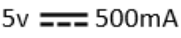




## 7. Glossary of Terms



### 7.1 Acronyms, Abbreviation and Definitions

<b>Acronyms or Abbreviations</b>	<b>Definitions</b>
<b>AC</b>	Alternating Current
<b>BSN</b>	Refers to the SPEAC® Laptop Base Station, and, in some contexts, the combination of the SPEAC® Laptop Base Station and AC power adapter.
<b>CLASS II</b>	Refers to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective grounding or reliance upon installation conditions.
<b>Contraindication</b>	Condition or factor that serves as a reason to withhold a certain medical treatment.
<b>DD</b>	Refers to the SPEAC® Detection Device, in some contexts, the combination of the Detection Device and electrode.
<b>EMG</b>	Electromyography
<b>GTC Seizure</b>	Generalized Tonic-Clonic Seizure
<b>IP Code/ IP Classification</b>	The Ingress Protection Code classifies and rates the degree of protection provided against the intrusion (including body parts such as hands and fingers), dust, accidental contact, and water by mechanical casings and electrical enclosures.
<b>Applied Part(s)</b>	Part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function
<b>Operator</b>	Refers to the person handling the equipment. The patient is also considered an Operator for the functions related to the use of the SPEAC® Detection Device including the daily maintenance described in section 18.
<b>Patient</b>	Refers to the person to whom a physician has prescribed the SPEAC® System. The patient is also considered an Operator for the functions related to the use of the Detection Device including the daily maintenance described in Section 18.
<b>PCBA</b>	Printed Circuit Board Assembly
<b>RF</b>	Radio Frequency
<b>RH</b>	Relative Humidity
<b>sEMG</b>	Surface Electromyography (non-invasive)

<b>SPEAC® System</b>	The product brand name for the Brain Sentinel® Generalized Tonic-Clonic Seizure Detection and Warning System. SPEAC® System = <b>S</b> ensing, <b>P</b> ortable, <b>E</b> MG, <b>A</b> nalysis, <b>C</b> haracterization System
<b>Type BF</b>	Type BF is a classification used generally for devices that have been electrically connected to a Patient but not directly to the heart.
<b>UI</b>	User Interface
<b>USB</b>	Universal Serial Bus

## 7.2 Internationally Recognized Symbols and Markings

Symbol	Meaning	Reference
	This symbol is used on the SPEAC® Detection Device and the SPEAC® Laptop Base Station indicating the patient and operator must consult the accompanying documents prior to using this medical device.	ISO 7010-M002 Refer to instruction manual/booklet
	This symbol is used in the United States to show that federal law restricts this device to sale, distribution, and use by or on order of a licensed physician.	
	This symbol is used on the electrode package indicating that the electrodes are a single use item.	ISO 7000-1051 Do not reuse
	This symbol is used on the SPEAC® Detection Device indicating that the applied part complies with the IEC 60601-1 standard regarding electrical shock and leakage currents.	IEC 60417-5333 Type BF applied part
	This symbol is used on the SPEAC® Detection Device indicating the SPEAC® Detection Device includes an RF transmitter.	IEC 60417-5140 Non-ionizing radiation
5v  500mA	This symbol indicates the SPEAC® Detection Device is powered by direct current. 5v and 500mA.	IEC 60601-1
	This symbol is used on the SPEAC® Detection Device indicating the SPEAC® Detection Device should not be placed in the regular waste stream. To dispose of the device contact Brain Sentinel®. See section 5 for contact information.	WEEE Directive (2012/19/EU)
	This symbol appears on the Panic control button on the SPEAC® Detection Device.	IEC 60417-5013
	This symbol appears on the Cancel control button on the SPEAC® Detection Device.	IEC 60417-5576
	This symbol is used on the SPEAC® Laptop Base Station label and is followed by the manufacturer name and address.	ISO 7000-3082

	This symbol is used on the SPEAC® Laptop Base Station label and describes the date the device was manufactured	ISO 7000 Manufacturer
<b>REF</b>	This symbol is used on the SPEAC® Laptop Base Station label and is followed by the model/type number, name and version.	ISO 7000-2493 Catalog Number
<b>SN</b>	This symbol is used on the SPEAC® Laptop Base Station label and is followed by the serial number	ISO 7000-2498
	This symbol indicates the manufacturer's declaration that the product complies with the essential health and safety requirements of the relevant European health, safety and environmental protection legislation. This product conforms with the Medical Device Directive, Council Directive 93/42/EEC: June 14, 1993, as amended by 2007/47/07 (as applicable) following the provisions of Annex II, when it bears the following CE Mark of Conformity.	CE marking certification

### 7.3 Other Markings

#### 7.3.1 Brain Sentinel, Inc. Markings

Brain Sentinel® labels are added to the laptop identifying the following:

- Manufacturer: Brain Sentinel®
- Model: SPEAC® System
- Serial #: <unique>
- Refer to instruction manual
- SW Version: see SPEAC® Laptop Base Station.

#### 7.3.2 SPEAC® Detection Device Identification and Markings

- Manufacturer: Brain Sentinel®
- Model: SPEAC® System by Brain Sentinel®
- Serial #: Located on back of SPEAC® Detection Device enclosure
- VA Rating: 500mA at 5VDC;
- SW Version: located on SPEAC® BaseStationApp.
- IP Classification: IP67, located in accompanying documents
- Consult Accompanying Documents (ISO 7010-M002)
- Non-ionizing Radiation (ISO 60417-5140)
- Type BF Applied Part
- FCC ID: located on back of device.
- The “Head Direction” icon seen here and located at back of Detection Device indicates that the



symbol should be oriented toward the patient's head to help ensure proper placement.

### 7.3.3 SPEAC<sup>®</sup> Laptop Base Station Markings

- Manufacturer: Acer America Corporation
- Model Number: E3-111-P60S
- Marketing Name: Aspire E11
- DC Rating: 2.5A at 19VDC
- S/N: <unique>
- SNID: <unique>
- Numerous regulatory markings

### 7.3.4 Access Point/Wireless Router Identifications and Markings

- Manufacturer: CradlePoint
- Model Name: CradlePoint router
- Model Number: COR IBR600LE
- DC Rating: 1.5A at 12VDC
- S/N: <unique>
- SNID: <unique>
- Numerous regulatory markings

### 7.3.5 Other Hardware Markings

- Manufacturer: Emerson
- Model #: DP4018N2M
- Required regulatory and standard markings.

### 7.3.6 Software Markings

- Windows<sup>®</sup> 8.1 Starter label



The SPEAC® System, a Generalized Tonic-Clonic Seizure Detection and Warning System, is manufactured by:

Brain Sentinel, Inc.

8023 Vantage Dr.

Suite 216

San Antonio, TX 78212

Brain Sentinel's 24-Hour Customer Service line is: 1-855-275-5424, Extension 3.

Web Site: [www.BrainSentinel.com](http://www.BrainSentinel.com)